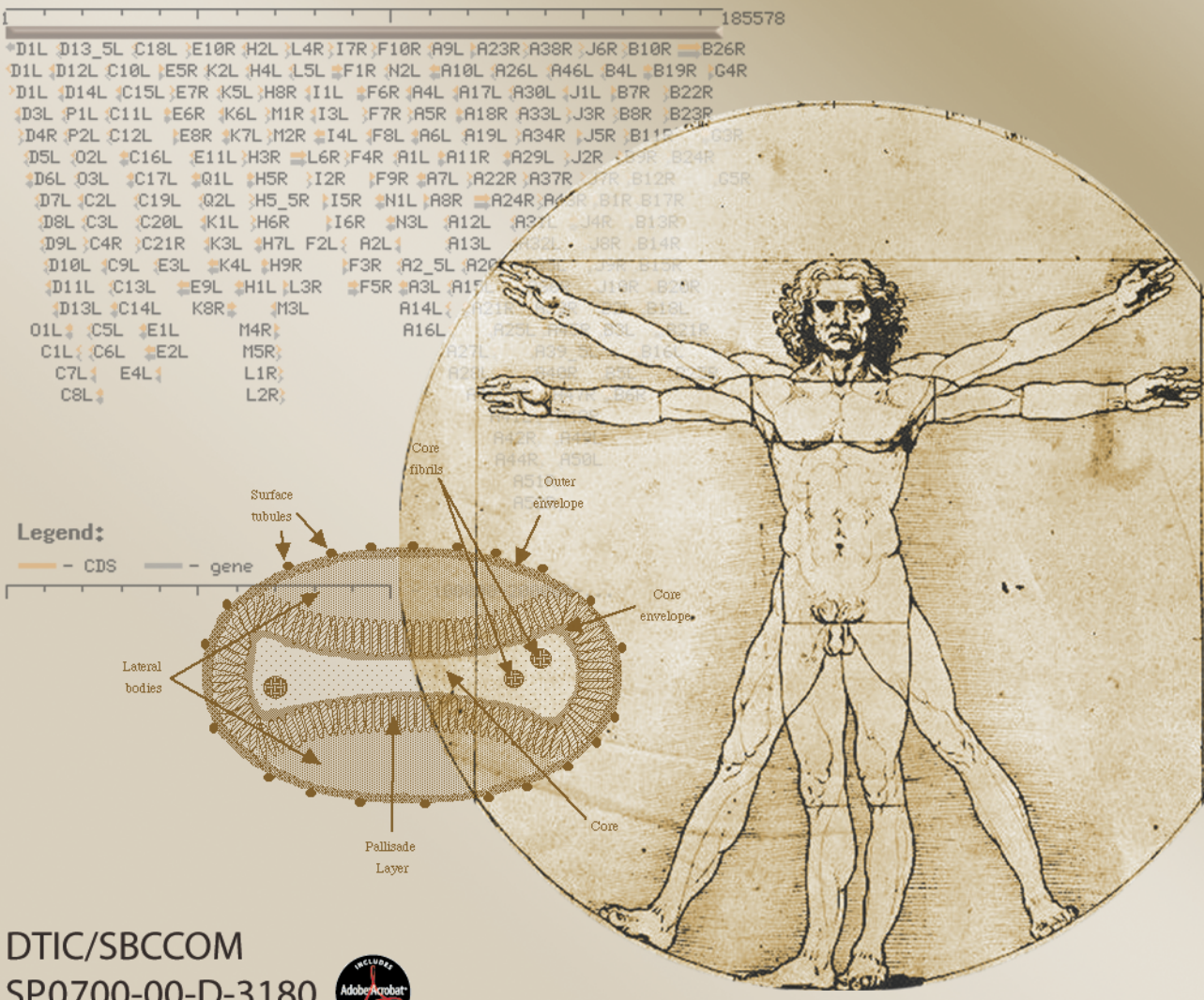
SBCCOM BIOLOGICAL WARFARE
IMPROVED RESPONSE PROGRAM

CDC/DoD
Smallpox Workshop

Held on April 17-19, 2000



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FINAL REPORT

of the

Biological Warfare Improved Response Program (BW-IRP)

CDC/DoD Smallpox Workshop

to

U.S. Army Soldier and Biological Chemical Command (SBCCOM)

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1. INTRODUCTION

In March 1995, members of the Japanese cult Aum Shinrikyo attacked the Tokyo subway with the chemical warfare nerve agent sarin. The incident captured international headlines, sensitizing governmental leaders around the world to the possibilities of the terrorist use of weapons of mass destruction (WMD). In response to this threat, the 104th U.S. Congress passed Public Law 104-210, the National Defense Authorization Act for Fiscal Year 1997, which contained Title XIV–Defense Against Weapons of Mass Destruction. In addition to providing our nation's first responders with preparedness training against weapons of mass destruction, Section 1415 of Title XIV stated that "The Secretary of Defense shall develop and carry out a program for testing and improving the responses of Federal, State and Local agencies to emergencies involving biological weapons and related materials and emergencies involving chemical weapons and related materials."

To support this legislation and the Department of Defense, the U.S. Army Soldier and Biological Chemical Command, in partnership with the Department of Health and Human Services (DHHS), the Federal Emergency Management Agency (FEMA), the Federal Bureau of Investigation (FBI), the Environmental Protection Agency, and the Department of Energy, developed a Biological Warfare (BW) Improved Response Program (IRP). This partnership was formed to assist all agencies with their particular responsibilities in responding to a biological incident. For example, the DHHS is the lead Federal agency to plan and prepare for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction (Presidential Decision Directive 62). A companion chemical warfare IRP is focusing on enhancing responder protection and detection and on mass casualty decontamination.

The BW IRP is a multi-year initiative that aims to identify and demonstrate the best practical approaches to improve BW domestic preparedness. A multi-agency team comprising emergency responders, emergency managers, technical experts, and policy planners from Federal, State and Local agencies from around the country was assembled to execute the program. New York City was a full partner in this effort, along with the State of New York and the New York National Guard. In addition to the federal agencies mentioned above, the U.S Department of Agriculture participated throughout the program. The primary products from the BW IRP effort to date include a BW response plan (template, a decision tree, and a prioritized list of response gaps and improvement concepts). The template and the decision tree are being evaluated through a series of local workshops at three cities to determine their applicability and scalability to varying locations and demographics. Additionally, another set of workshops is being used to evaluate the most pressing gaps to determine ways to bridge requirements with technology and improve communications throughout the regulatory and response communities.

The BW IRP participants determined that there is a gap in the handling of communicable diseases. A response to a bioterrorist incident involving a communicable disease agent is substantially complicated by the possible diverse sources of infection.

In an effort to close this gap, SBCCOM teamed with the Centers for Disease Control and Prevention (CDC) to sponsor a workshop in April 2000. The goal of the workshop was

> "To refine the CDC Smallpox Control Plan/Strategy by applying it against a manufactured outbreak scenario. Specific areas to be evaluated [were] vaccination, quarantine/isolation, and medical surveillance. These focus areas will provide information that is valuable to CDC to improve their plan and help to better define unique elements of a response to an event involving use of a communicable disease agent."

Both SBCCOM and CDC recognize that when a communicable disease agent is used in bioterrorism, unique issues must be considered not only by the medical and public health communities, but also by many other members of the emergency response team. Therefore, SBCCOM and CDC assembled a panel of law enforcement and medical/public health personnel, emergency responders, risk communicators and fire and legal professionals to identify potential solutions to the problem of how to respond to a communicable disease agent. This report is a product of the panel's discussions and is intended to assist CDC and the medical/public health community in resolving the issues that surround the use of a communicable disease in a bioterrorism scenario. The contents of this report should not be viewed as policy directives, but rather as recommendations and guidance for resolving the complications presented by communicable diseases and their spread.

The report is divided into three primary sections. The first section discusses the process used to arrive at the conclusions in this report. The second section briefly discusses the focus areas described in the purpose, and the third section provides the proposed segments of the decision tree, based on the breakout groups' discussions, and recommendations on the response template as they relate to a communicable disease.

2. WORKSHOP PROCESS

The Workshop (see Appendix A for agenda) convened a group of more than 40 professionals (see Appendix B) from across the country. To represent the diverse perspectives of the various levels of government who would be involved in responding to a bioterrorism incident, individuals from local, state, and federal agencies, as well representatives from professional groups, were asked to participate in the workshop process.

The Workshop was conducted in two phases: briefing and breakout groups. In the briefing phase (see Appendix C), the participants listened to presentations on the background/purpose of the BW IRP and the decision tree. Next they were given an overview of CDC initiatives, some background on the smallpox vaccine stockpile, a basic primer on smallpox, and a brief discussion of the draft CDC smallpox strategy. These briefings were intended to ensure that all workshop participants had a basic understanding of smallpox as a disease, its general characteristics, and treatment and prophylaxis. Additionally, the participants were provided with a hypothetical smallpox incident scenario (see Appendix D) to use as a frame of reference for the focus areas; it was not designed to exercise their response to the incident.

The breakout groups were used to identify potential solutions to the complicated problems of vaccination, isolation/quarantine, and enhanced medical surveillance for smallpox. Each breakout group was composed of a cross-section of governmental levels to ensure that all perspectives were examined. Members of each breakout group were given a series of questions to frame their responses to a smallpox incident (see Appendix E) within their respective focus areas (Vaccination, Medical Surveillance and Isolational/Quarantine). After the groups had deliberated on the focus issues, participants reconvened as a single group and each breakout group presented its findings and took comments.

3. MEDICAL SURVEILLANCE

Effective medical surveillance enables early detection and timely response and offers a greater chance to control the spread of a communicable disease. Surveillance can detect anomalies in the normal indicators, such as outbreaks unusual for a particular season, and prompt a transition from passive surveillance to an expanded or active surveillance. Once a bioterrorist event is suspected, hospital emergency departments, physicians' offices, and other treatment facilities such as walk-in clinics will work with epidemiological investigators to ascertain the context and possible cause of the abnormal indicator(s). During active surveillance, surrounding areas are monitored for the presence or absence of cases. Indications of a wider spread of the disease may initiate national surveillance.

The medical surveillance breakout group discussed surveillance methods and procedures as well as reporting activities such as contact-tracing that would improve the existing local and national infrastructure.

The group consensus was that planning, communication, and education of the first responders and the general public needs to be improved across the nation. Local and state public health departments must be proactive and work with the CDC to create and refine case definitions for potential biological agents, especially those that are contagious. Jurisdictions should also be aware of the additional diagnostic laboratories that are available presently (or will be in the near future) to supplement the CDC and U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID).

Successful medical surveillance is dependent on a number of factors. Local public health officials and the local and federal law enforcement communities must maintain good relationships that will ensure trust and a free flow of information during a crisis. It is essential to make these contacts in advance of an outbreak so that crisis calls elicit appropriate, productive responses. It is equally important for them to understand each other's roles so that federal and local authorities can avoid duplicating efforts and work as a seamless team to save lives and reduce suffering. Continuous education is needed to sensitize the medical community to the signs of an outbreak and prompt local physicians to contact the local Public Health Department as soon as there is appropriate suspicion of a reportable disease. However important continuing medical education may be, it is still challenging to encourage busy physicians to participate in training that may not appear immediately relevant to them. Therefore, infection control and emergency medical response groups are good personnel to target initially to distribute diagnostic information. Once an identifiable case occurs, a meeting designed to educate physicians will draw a full house, even from the private sector.

The requirements for the type of information and frequency of reporting across local, state, and federal levels needs to be established prior to an event. The tools selected for reporting, such as electronic mail or a secure web site on the Internet, need to be fast, efficient, and reliable. Due attention needs to be given to training response personnel to enhance their awareness, trigger recognition, and assist them in expanded

surveillance. The responsibilities of these response personnel should be defined and validated in the planning stage. Once a contagious case is identified, the public should receive timely, accurate information from a credible source, including necessary precautions and ways for them to help with the surveillance and epidemiological investigations. This information should be disseminated in multiple languages that are appropriate to area demographics.

The CDC will be an important presence in coordinating activities and information from states with or without cases. However, local authorities need to remember that in case of a bioterrorism event, the CDC will not initiate a visit or response; they must be requested to assist in the surveillance effort.

3.1 Initiation of Surveillance

Generally, there are two categories of surveillance: passive surveillance and active, or expanded surveillance. Passive surveillance is always operating and sensitive to unusual situations. Active or expanded surveillance is initiated after suspicion is raised or in response to a warning or a “first case“ diagnosis of a transmissible event.

Effective surveillance is hampered by uncertainty about indicators to monitor regularly. For example, because smallpox was declared eradicated worldwide in 1977, it is bound to be misdiagnosed simply because it has not been seen nor is it expected by many contemporary physicians (an exception to this scenario would be a warning in advance of a smallpox release, which would alert health care professionals to smallpox's symptoms). Faced with a suspicious disease, it is likely that an infection control professional (ICP) or an infectious disease specialist would be consulted. Given either a presumptive diagnosis by the ICP or uncertainty about the disease, the public health department would be contacted, who would then call state and federal authorities. A presumptive diagnosis of an unusual agent would be the threshold for expanded surveillance (e.g., the clinician responding to the recent West Nile Virus incident had two patients).

A CDC directive states that a single case of smallpox would constitute an epidemic. To initiate national surveillance, a public announcement would be made by a group that would include a public official for that area, a public health/medical officer, the state epidemiologist, and a law enforcement official, but the CDC would be the chief coordinator in a national surveillance effort.

Awareness of unique symptoms will need to be raised by training clinicians. For example, adults presenting with chicken pox under suspect circumstances, such as a history of the disease in childhood, should raise the question of smallpox and key the practitioner to review the symptoms more closely. Seasonally unusual situations, such as many cases with flu-like symptoms presenting in non-flu season (anthrax scenario), should also raise a flag.

Increased pharmaceutical sales of a particular type of product can also be used as an indicator of an unusual disease situation, particularly when purchase or ordering information is available electronically for easy tracking and dissemination. Unusually high sales of over-the-counter anti-diarrheal products have served as a clue in the past for an outbreak of *Cryptosporidium*. Flu medication may show an increase in prescription sales even when the flu is not present, which might suggest the presence of smallpox or other disease. Other events that might serve as indications of a bio-terrorist incident are large numbers of patients with similar symptoms, similar symptoms in a diverse cross-section of the community, and dead or dying animals in unusual numbers.

It would, of course, be valuable to isolate a suspicious virus, but this can take time, and samples must go to the CDC or USAMRIID for processing.

Whole-team education is needed for Emergency Medical Service (EMS) and Emergency Room (ER) Teams, ICP, clinical physicians, public health officials, and hospitals, in particular, diagnostic training for chickenpox versus smallpox. The breakout group recommended that infectious disease practitioners be trained to diagnose bioterrorism-associated illnesses using a "train the trainers" approach, which will reduce costs. Annual training could be given thereafter to cover new health care practitioners.The breakout group suggested diagnostic training to increase awareness; communication between public health offices, hospitals, and private practitioners; and regular meetings with communicable disease practitioners to discuss occurrences of unusual symptoms. Ambulance and fire safety organizations also need to be a part of the response system by reporting the refusal of victims to accept transport (911 systems in New York can use such calls as a trigger) along with the response calls.

3.2 Parameters for Surveillance

Case definitions (confirmed, suspected, etc.) for biological agents in a local, state, or national surveillance program must be specific and may have to be developed. Table 1 gives the signs that should cause suspicion of smallpox. For smallpox, past surveillance included no case definitions but rather visual recognition cards. Presently, the chicken pox definition has been modified to create a smallpox definition. The CDC develops a case definition and refines it when cases occur. CDC representatives stated, in the meeting, that the national definition for smallpox will be simple: fever with pustular rash.

Table 1: Signs that should cause suspicion of smallpox

• Fever >100 F with rash either present or within the last 2 weeks • Pharmaceuticals prescribed or issued for chicken pox • A number of suspected cases of chicken pox • Reports of rashes, especially a rash on the extremities, spreading to the trunk

The parameters for national medical surveillance of an outbreak will be based on laboratory confirmed cases from the CDC or USAMRIID, and confirmed cases would lead to more stringent requirements for states with suspected cases.
The group considered the frequency of local and state surveillance reporting and concluded that immediate reports of suspected cases should be made, followed by reports of subsequent individual cases in active areas. A CDC directive makes bioterrorism diseases immediately reportable. The CDC also wants hospitals to send their information to their local public health department. ICPs can conduct a point prevalence study to examine all criteria in a short period of time. Daily updates are sufficient for areas not immediately affected by the disease. Surveillance has to be performed to confirm presence or absence of cases, including active regional surveillance in areas around the initial case, immediate reporting of actual or suspected cases to public health department, and daily calls to hospitals by the health department to poll for information. States with a confirmed case and their contiguous states would be on more active surveillance than other states.

The frequency of reporting from states during national surveillance would vary according to the situation, but reporting would probably be more frequent at first and would then taper off as CDC personnel are placed around the country. Real-time reporting to the CDC is important to provide vaccine and support to match needs and mobilize federal resources. Ongoing status reports would be sent from the CDC to medical and law enforcement groups, and other groups would be informed through more general CDC media reports and bulletins.

A hospital can be designated for suspected cases, and public health can poll hospitals, emergency rooms, infection control personnel, clinics, and private practitioners for suspected cases in a multi-state area. The group also suggested obtaining a list of the National Disaster Medical System (NDMS) beds available as isolation beds or designating an armory or gymnasium as a center for isolation. Separation of infected and non-infected patients will be important in a hospital/facility.

Jurisdictions should plan to collect several types of data for reporting in local and state surveillance (see Table 2). Admission sheet data from hospitals should include personal information (name, location, contact numbers of family) and could be transmitted by phone, fax or email to the public health department. Along with contact data, surveillance personnel should plan to collect descriptions of symptoms and cases being treated by dermatologists or pediatricians for rashes. Family members and contacts of patients should be interviewed, vaccinated, and placed under fever surveillance with follow-up. EMS runs and transportation refusals could also be responsible for spreading a disease and should be tracked. Travel histories of patients should be traced. In the event of a confirmed bioterrorism incident, reports, anonymous tips, and other information would be shared with law enforcement. For smallpox, any outbreak would be considered a deliberate release requiring two types of information for response: immediate medical information to stop the spread and information to conduct an epidemiological study and find the source. As cases increase, doctors have less time

to gather information, so plans to collect data must be implemented initially with existing personnel and a central location must be designated to receive the information.

Table 2: Types of data to be reported in surveillance

• Admission sheet data from hospitals • Descriptions of symptoms and cases being treated by dermatologists and pediatricians • EMS runs, particularly transportation refusals • Travel histories of patients (very important in national surveillance) • Anonymous tips or reports (of interest to law enforcement for bioterrorism investigation)

During national surveillance operations, the CDC will need basic demographic information as well as data on the number of cases from states. Cross reporting would occur initially but would decrease as the CDC placed more people at field locations. Names and numbers would be collected initially, and at a later formal surveillance level, only numbers would be collected. The travel history of cases and contacts would also become very important in national surveillance. The CDC collects data from the state and local level. A central collection group gathers data and works with the World Health Organization (WHO) for international tracking. Therefore, the CDC will have information on the number of people affected, and local authorities will have more detailed information dealing with the specifics of each individual case.

Medical and public health surveillance personnel should gather their data from many medical and non-medical sources for their investigation (see Table 3). The more obvious medical and public health sources include EMS (including calls resulting in refusal to be transported by the patient): health departments; health care workers (ICP, emergency room personnel, infectious disease personnel); pediatricians and dermatologists (tending patients with rashes or areas of hemorrhage); laboratories; and medical examiners (filing reports of unexplained deaths). Pharmacies (with increased sales of chicken pox related remedies or anti-viral compounds) or morticians (with cases where family did not report, victim lived alone, or a rash was seen only upon viewing the whole body) could also provide relevant information. Finally, Ultra High Frequency/Very High Frequency (UHF/VHF) EMS broadcasts and air, land, or sea transportation health personnel could be surveyed for travelers reporting being unwell when traveling but not detained at port for medical examination. During national surveillance, the CDC would receive information from state public health departments, which would have received their information from hospital and health department personnel.

Table 3: Sources of medical and non-medical information for surveillance

• EMS runs and broadcasts (particularly "refusal to transport" calls) • Health departments and health care workers (ICP, emergency room personnel, infectious disease personnel) • Pediatricians and dermatologists • Medical examiners (particularly reports of unexplained deaths) • Pharmacies (particularly increased sales of chicken pox or other anti-viral remedies) • Morticians • Veterinarians (in some cases) • Air, land, or sea transportation health personnel

As a part of national surveillance, the CDC would also track the number of case-related deaths; the recoveries of people released from surveillance at a local level; and any disease sequelae, such as numbers of persons blinded by smallpox, which would be considered a new crisis and handled separately.

Methods of reporting medical surveillance data at all levels should be fast, efficient, and accurate, such as telephone, fax, electronic mail, or Internet.

3.3 Personnel Resources for Active Surveillance

The group formulated an extensive list of the types of personnel that would be needed for organized and successful active medical surveillance operations (see Table 4). Epidemiologists (CDC, State and Local) and epidemiological-trained personnel should ideally have international expertise from places that have experienced smallpox outbreaks. Infection control personnel, although they will probably be involved in active patient care and not available for surveillance tasks, should be identified, particularly members of the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC). Medical clerks can field and prioritize phone calls, and data entry personnel can record information. Retired medical or nursing personnel and other appropriately trained retirees and medical or nursing students could be activated, as could volunteer organizations such as the Red Cross, Salvation Army, or American Association of Retired Persons (AARP). A professional emergency management team, including legal, communication, and public information officers and social workers, partnered with infection control and infectious disease expertise as well as FBI, public health departments, and front line health care workers will be crucial. State and local assets such as Metropolitan Medical Response System (MMRS) Teams and WMD Civil Support Teams (CST) (formerly known as RAID teams), as well as representatives from the US Department of Agriculture, would also be available.

Table 4: Types of personnel needed for active medical surveillance

• Epidemiologists • Infection control personnel (ICP) • Medical clerks and data entry personnel • Retired or student medical personnel (supplemental medical assistance) • Volunteer organizations such as the Red Cross or Salvation Army • Emergency management teams • Public health departments • FBI • MMRS and WMD-CST teams

Personnel working in medical surveillance should be trained with the goal of heightening their awareness of bioterrorism. Such training will enhance communications among public health officials and hospitals, the health community, authorities, and the general public. Training must include basic, multilingual presentations ("Smallpox 101"), table top exercises with realistic scenarios applicable to specific jurisdictions, and instruction in the software that will be used for record keeping, such as tracking databases, electronic data transit, and system setup and maintenance. Surveillance personnel should be familiar with agent characteristics such as how to distinguish smallpox from chicken pox, modes of transmission, and appropriate methods for control.. The wide publication of the distinguishing characteristics of the two diseases will help to identify additional patients and contacts. To streamline data collection and reporting, trainers should establish a questionnaire for contact-tracing and outline method(s) for reporting to the public health department (fax/email coversheet of medical chart). Concerns of working with the media in times of crisis should be outlined by a public official and should have the backing of a clinical person who knows the medical facts. Confidentiality should be reiterated; this is vital to avoid legal complications. Responders (EMTs, police, etc.) and their families should be assured that with training, vaccination, and proper use of protective equipment, they will remain safe from the disease. Finally, lessons learned throughout the course of training should be shared regularly with other agencies.

At the national level of surveillance, the CDC would use its own fully trained surveillance personnel and analysts to balance the needs of all the states involved. States can use CDC personnel for contact-tracing, but states will also need people at the local level who know the area (system already exists to track communicable diseases). Law enforcement and federal investigators may be needed to help with surveillance.

The group stressed that, along with clear and complete communication between medical surveillance personnel, communication with the general public should be frequent and thorough. Facts should be delivered simply, and pictures (of smallpox rashes, for example) should be provided whenever possible. Precautions to take to avoid spreading the disease within a family and during encounters with the public

should be consistent, and, as much as possible, people should be directed to a single authoritative source such as the CDC for more information.

3.4 Other Surveillance Issues

Surveillance at the major transportation nodes providing access to and from the centers of an outbreak is also important, particularly in national surveillance operations. For example, passengers coming off a plane could be questioned as they exit. Seven major airports have a CDC quarantine person on site or a contract with a suitably designated medical person. Airline personnel could be trained to identify possible patients and make sure they are examined. However, legal training may be needed to handle a situation where a traveler is ill and wants to leave without examination.

Frequently updated reports of numbers of cases and the size and locations of outbreaks should be available for travelers. Travelers may also need to be vaccinated and travel with an official document for proof of vaccination.

It is impossible to pre-determine the duration of expanded surveillance. The operating budget would not likely be a limiting factor because the Federal government (probably FEMA) would provide the funds for national surveillance and local response. The duration would be contingent on the situation and a joint local, state, and federal decision. Hospital polling and the heightened awareness of providers would persist for some time because smallpox can occur in waves of infection, and national or international travel has the potential to bring it back to a community that had previously recovered.

4. VACCINATION STRATEGIES

A carefully planned and implemented vaccination program is critical to containing a smallpox outbreak. The breakout group assigned to address vaccination strategies was asked to consider both a contact-tracing program and a mass vaccination program. Contact-tracing involves interviewing confirmed cases to determine from their histories who else they might have contacted and exposed to the infectious agent. These "contacts" are then sought out and vaccinated. A mass vaccination program simply attempts to vaccinate everyone in a given population who may potentially be exposed to the infectious agent.

After some discussion, the group agreed that while fear of the disease and political pressure might in some cases lead to a mass vaccination program, a contact-tracing program is always preferable and more efficient, particularly when vaccine supplies are limited. The group also felt that the medical risks and benefits of each individual vaccination should be weighed, and this risk-benefit analysis should not be abandoned in favor of indiscriminate vaccination. The group acknowledged that as the number of exposures increases, the accuracy of contact-tracing will decrease and become necessarily less precise, but it felt strongly that contact-tracing should not be abandoned at any point for mass vaccination. To discourage a mass vaccination program, the group recommended educating politicians in advance. More extensive materials should be prepared for the media to respond to its demands for information during a crisis. Should the decision be made to undertake mass vaccination, the media will be a critical ally of the medical and public health community in its efforts to assure that it is done correctly.

The vaccination strategies group was asked to address a specific list of questions (contained in Appendix E) in its discussion, and it expanded these questions to make the following recommendations.

4.1 Initiation Criteria

The criteria used to initiate a vaccination program would vary depending on whether the attack was announced or unannounced. In the event of an unannounced release of smallpox virus, a vaccination program would be initiated after a clinical case of smallpox was confirmed by laboratory testing at USAMRIID or CDC. Smallpox might be confirmed by Polymerace Chain Reaction (PCR) or viral isolation, with or without electron microscopy. The group noted that there would be a period of time, probably several hours, between the first suspicion of smallpox and inclusion of smallpox in a differential diagnosis and the laboratory confirmation from USAMRIID or CDC. During that time, law enforcement officials would be alerted as to the possibility of a smallpox outbreak and some contact-tracing, discussed below, could also begin.

In the event of an announced release of smallpox virus, the CDC, in conjunction with law enforcement officials, would make a judgement as to the validity of the claim. If

environmental sampling or tests of a suspected release apparatus showed the presence of virus, a limited vaccination program might be initiated.

4.2 Personnel Requirements

The desired qualities for contact-tracers are listed in Table 5. Ideally, trained epidemiologists would undertake contact-tracing and they would have actual experience with diseases that require contact-tracing, such as measles, tuberculosis, sexually transmitted diseases (STD), or meningococcal meningitis. Medical training would also be ideal for persons conducting contact-tracing. The group recognized that in some outbreak situations, there might not be enough trained investigators in the affected area to do the necessary contact-tracing. In this case, additional medically trained personnel could be recruited from doctors, nurses, nurse practitioners, dentists, physician's assistants, veterinarians, or military medical or preventive medicine officers in the area.

Table 5: Desired qualities for contact-tracers

• Experience with diseases that require contact-tracing (measles, tuberculosis, STDs) • Medical training (physicians, nurses, veterinarians, dentists, military medical or public health) • Familiarity with local geography, modes of transportation, roadways • Good interpersonal skills, ability to gain trust and obtain information from strangers

However, because a critical medical infrastructure must always be maintained, that is, the medical system must continue to perform day-to-day medical functions unrelated to the outbreak, contact-tracers will likely have to be recruited from other geographical areas or from groups other than specifically trained epidemiological investigators. Contact-tracers from other geographic areas must have some familiarization with the local geography, modes of transportation, roadways, etc.

The group agreed that good interpersonal skills and the ability to gain trust and obtain information from strangers are the primary criteria for contact-tracers lacking a formal background in epidemiology. Other important skills may include familiarity with languages other than English and cultural aspects of the affected population. A basic course in the medical and epidemiological aspects of smallpox and its spread could then prepare these contact-tracers to collect adequate data and allow them to serve as sources of information to allay public fears. The group also noted that the news media could be helpful in teaching people about the mechanism of contracting smallpox as well as explaining that there is no specific medical treatment. Such education, distributed on television or by other means, could help to discourage unnecessary runs on medical facilities. The media might also help to educate people why mass vaccination is not desirable and why some people should not receive vaccination unless they were actually exposed to smallpox virus (discussed in more detail below).

Several members of the group noted that although law enforcement officials assisting with contact-tracing might generate anxiety in some sections of the population, they would be very helpful in obtaining lists of potential contacts that might be protected in normal, non-crisis operations (e.g., passenger roster from an aircraft).

The consensus of the group was that the most efficient way to proceed was to have the contact-tracers also administer vaccinations. Vaccination training is relatively simple and can be given in less than an hour, but a policy as to who is legally credentialed to administer the vaccine must be established in writing. Furthermore, part of the process of training contact-tracers in how to administer the vaccine should be their credentialing at the end of the training. The group recommended that a roster of qualified contract tracers be established well before an event and updated periodically. There are some potential problems with this approach as it necessitates keeping the roster up-to-date. Due to the transient nature of our society, this is virtually impossible. An alternate approach suggested during the comment period was to develop a roster of organizations that are comprised of people with the appropriate skills to serve as caseworkers. It would then be necessary to retain current data on only the leadership or contact points for the organization. If a bio-terrorist event were to occur, then the organizations would be canvassed to secure the necessary caseworkers.
In the event that contact-tracers could not vaccinate contacts as they were identified, it might be necessary to vaccinate contacts at a common interview site or pre-designated central facility such as a school or shopping mall.

The number of exposed contacts could be used as a basis for deciding whether to vaccinate contacts as they are identified or, alternately, to send them to a central vaccination site. At a central site, a few trained medical people could explain the risks and benefits of vaccination to a large audience, and a few trained individuals could vaccinate large numbers of individuals quickly. Such a setup would obviate the need for contact-tracers to have three medical credentials: for vaccinating, acting as educators, and screening for contraindications.

The group recognized the need to properly document vaccinations. At the same time, the group recognized that the documentation process would be the most time-consuming part of vaccination. For large vaccination centers, documentation is the rate-limiting step, but if individuals fill out documentation while standing in line, they can increase the efficiency of the process. In addition, vaccination documentation must satisfy international requirements for anyone needing to leave the country within a short time period after the smallpox outbreak has been identified.

4.3 Follow-up

A follow-up program needs to be put in place to confirm effectiveness of the vaccination. At the time of vaccination, individuals must provide a phone number or other information that will enable them to be contacted for vaccine reading six or seven days after they leave the vaccination site. For small numbers of vaccinated individuals, it may be possible to read the vaccination in the individuals' homes, but with larger numbers, it

may be more efficient to read the vaccines at a central location. The documentation system must also include a means of identifying people who don't return for their follow-up readings. Since presumably they have been exposed, individuals should be briefed at the time of vaccination as to the expected symptoms of and effects of the vaccine, including adverse reactions. However, since presumably they have been exposed to smallpox, they must also be briefed on what to expect if they develop the disease. The most reliable indications are fever and flu-like symptoms. Patients experiencing these symptoms could report them to a designated referral center, but it was noted that not all potential patients would have a thermometer or understand how to use it or understand the criteria for a fever.

4.4 Use of Vaccine Immune Globulin

Historically, patients with risk factors for complications from the vaccine experienced lower rates of complications when they were given vaccine immune globulin (VIG). However, because of the presently limited supply of VIG, it should be reserved only for patients with potentially life-threatening complications. To the extent possible, the criteria for using VIG should be standardized, but in some cases, subjective medical judgement may be required. For example, a severe case of eczema vaccinatum might warrant use of VIG, whereas a mild case would not. The consensus of the group was that the ultimate decision for using VIG should be left in the hands of the senior state public health official with assistance from CDC officials.

4.5 Screening for Contraindications to Vaccination

The group agreed that because of the high probability that direct face-to-face contacts with infectious persons will themselves contract smallpox if not protected, there are no contraindications to vaccinating these direct contacts.

People who are contacts of contacts (who are asymptomatic), however, present a different situation (see Table 6). It is preferable not to vaccinate such persons if they are under one year of age, have eczema, or are pregnant or immunosuppressed. The population of immunosuppressed people includes not only Human Immunodeficiency Virus (HIV) positive patients but also those who are taking steroid drugs, are transplant recipients, or have end-stage renal disease. Medical practitioners in the group noted that the risk of miscarriage to pregnant women was not extensive; rather it was anecdotal and not well documented.

Table 6: Contraindications to smallpox vaccination

For Contacts	For Contacts of Contacts
NONE	• Patients under one year of age • Patients with eczema • Patients who are pregnant • Patients who are immunosuppressed, including those patients who are HIV-positive, are taking steroid drugs, are transplant recipients, or who have end-stage renal disease

The group recommended removing the contact of the contact from further potential exposure to the actual contact while they are monitored for symptoms and while the vaccination site is healing (to avoid exposure if the contact develops smallpox or exposure to the vaccination site that contains live virus). Once the incubation period has expired (17 days), then these people can resume contact with the contact. For example, if a family member is exposed and subsequently vaccinated and an immunocompromised person resides in the household, it may be desirable to move the immunocompromised person out of the house during the incubation period as a precaution to ensure the exposed family member does not develop the disease or get exposed to live virus from the vaccination site.

As a part of its advanced preparation for an outbreak, the CDC should prepare a compendium of information on smallpox vaccine contraindications which could be rapidly distributed should the need arise. Such an information packet could be electronic and "ready to go" rather than in paper form. Public announcements about vaccine contraindications should be made, and placards should be posted at vaccination sites. A screening questionnaire is also effective, but this may slow the vaccination process at centralized vaccination sites.

4.6 Refusal of Vaccine

Jurisdictions should expect that some contacts will refuse to take the vaccine. The group felt that while such people should not and probably could not be forced to be vaccinated, such individuals should nevertheless be isolated to prevent any spread of disease. Furthermore, the group felt that as a matter of policy and because of their short supply, neither VIG nor anti-viral drugs (if any licensed products become available) should be given to those who refuse vaccination.

4.7 Other Populations Who Should be Vaccinated

Some persons other than those who have been exposed to smallpox should be vaccinated, namely those who are at high occupational risk for contact. These persons include medical and other caregiving personnel, first responders and other response teams, laundry and mortuary personnel, clergy and elected officials who may desire contact with infected patients, and lab technicians performing diagnostic tests. Not all persons in these categories would be vaccinated. An assessment should be made of

their probability or need for contact with infected persons; those personnel with prior vaccination who would respond more quickly to the challenge may be considered for vaccination first. The policies should be established in advance of any possible outbreak.

4.8 Legal Issues

Some indemnification or hold-harmless mechanism should be established to compensate vaccine manufacturers and the medical personnel and institutions involved in the vaccination program. Compensation may also be needed for owners of buildings used for large vaccination efforts or hospitals that are used as smallpox hospitals.

4.9 Foreign Observers

Any smallpox outbreak may bring in foreign and/or WHO personnel as observers. WHO observers should be vaccinated if allowed to follow the vaccination programs process and progress.

5. CASE AND CONTACT ISOLATION

In addition to limiting the spread of smallpox with a strong medical surveillance program and a judicious vaccine strategy, spread can be limited by effectively isolating smallpox cases and contacts. The breakout group assigned to address case and contact isolation examined a variety of issues surrounding a small and a large smallpox outbreak. The group defined a small outbreak as one that can be controlled by a jurisdiction's hospitals without activating their emergency or disaster plans. A large outbreak was defined as one that requires activation of the hospital emergency or disaster plans. Because of the differences between the sizes and capabilities of individual jurisdictions, the group agreed that it would be difficult to define a small or large outbreak strictly by numbers.

The case and contact isolation group was asked to address a specific list of questions and, as a result of its discussion, made the following recommendations. A complete list of the group's questions can be found in Appendix E.

5.1 Isolation Strategies

The group developed its isolation strategy for five possible categories of patients, based upon how the group participants believed a smallpox outbreak would manifest in the medical system. The five categories include initial suspected cases, confirmed cases, suspected cases due to heightened awareness, close contacts, and questionable contacts. These categories assume that initial smallpox cases will arrive with a severe rash, high fever, and possibly a few lesions. In most instances, a physician is likely to diagnose the malady as a severe rash or chickenpox. However, the group believed the rash would be severe enough to raise concern in the hospital and potentially lead to isolation of the patient.

1. **Suspected Initial Case(s).** The suspected initial case(s) may not have fully manifested all the symptoms of smallpox but have some symptoms (i.e. rash) that would potentially alert a physician to consider an unusual illness such as smallpox or provide enough information to make a clinical diagnosis of smallpox. Suspected initial cases would be found in small outbreaks and the early stages of a large outbreak. The group believed that in most instances, these patients would arrive at a hospital and be treated there.
2. **Confirmed Case.** Confirmed cases have had laboratory confirmation of smallpox.
3. **Suspected Cases Due to Heightened Awareness.** Subsequent to the presentation of a strongly suspected or laboratory-confirmed case of smallpox, physicians may be able to clinically diagnose smallpox in patients exhibiting similar symptoms. This would include new patients entering the hospital as well as patients that were admitted around the same time as a suspected or confirmed smallpox case.
4. **Close Contacts.** Close contacts are individuals that have had close, face-to-face, personal contact with people that are suspected or confirmed to have

smallpox, such as family members, friends and/or co-workers that have interacted with the smallpox case for regular or extended periods of time.

5. **Questionable Contacts.** Questionable contacts may have had incidental or transient contact with a suspected or confirmed smallpox case. The group defined an incidental contact as someone who was possibly in the same building, neighborhood, etc., with the suspected individual but had no direct contact with the individual.

The group stated that isolation strategies would vary among these categories, yet generally they recommended against assembling any of the suspected smallpox cases in a single area such as a school gym, warehouse, or even a hospital. The rationale for this decision is that individuals who may not have been exposed to the infectious agent should not be put at risk of being exposed in an area with more likely cases. Placing a variety of suspected cases together could expose an individual to the smallpox virus whose immune system is weakened by some other ailment, especially early in the disease cycle. This is especially true in hospitals, where there are large numbers of immunocompromised individuals.

The group recommended few instances in which jurisdictions should cohort the different categories of smallpox cases across or within each of the categories (see Table 7). The only instance in which the group recommended isolating suspected and/or confirmed smallpox cases in a hospital would be for the initial cases during a small outbreak. The rationale for this is twofold. First, a preliminary diagnosis is more likely to occur in hospital emergency department than a private practitioner's office. While a physician may be unlikely to diagnose the case initially as smallpox, he or she may suspect an unusual infectious agent and want to isolate the patient as a precaution. Second, the number of initial cases that would present at the same time from a small outbreak could, in all probability, be handled adequately at a hospital, and the hospital could limit the public access for a small number of cases. Therefore, with the exception of the initial suspected and confirmed cases in a small outbreak, the group recommended isolation at the patients' homes or in a centralized facility that can effectively segregate potential smallpox cases.

The most significant difference between the isolation strategies for small vs. large outbreaks is where suspected and confirmed cases and contacts will be isolated, examined, and treated. Because of the lower number of patients in a small outbreak, the group recommended isolating individuals in their homes. Field public health representatives could then follow up with the infected individuals in their homes and conduct examinations, treatment, and contact tracing.

For a large outbreak, the group still recommended isolating the individuals, both sypmtomatic cases and direct contacts, in their homes. However, in a large outbreak, the greater number of potential patients would quickly exhaust the capacity of the public health system to send representatives into the field. To respond to the greater number of patients in a large outbreak, the group recommended establishing centralized neighborhood examination and treatment centers. Locations for these centers should

be chosen according to their capacity to hold a large number of people. Local fire stations, meeting halls, or schools were suggested. Direct contacts in a large outbreak could be isolated in their homes but still be able to seek treatment within the potentially affected area, thus minimizing the potential for spreading the smallpox virus to unaffected areas. This recommendation is principally for contacts, but it could be used for the suspected cases as well. In general, confirmed cases or highly suspected cases should not leave their homes if at all possible.

The group's second recommendation for a large outbreak was to isolate the suspected and confirmed cases in a single building. By doing so, public health officials could examine, treat and monitor individuals in a single location. Moreover, they would have an increased ability to control access to the individuals and limit their movements. Some potential facilities identified by the group include multi-family dwellings (apartments, condominiums, etc.), hotels, nursing homes, military facilities, local jails or prisons, and schools. If this recommendation was implemented, it would be essential to keep the suspected cases segregated from the confirmed cases to limit the spread of the disease.

These facilities were chosen by the group according to certain criteria necessary to isolate individuals (see Table 8). The most significant of these criteria is the need to independently ventilate each of the dwellings/rooms that contain suspected or confirmed cases, to limit the potential spread of the smallpox virus to others sheltered there. The group also considered the political ramifications of placing confirmed and suspected smallpox patients into isolation facilities but concluded that this issue needs to be addressed individually by each jurisdiction. Potential facilities and political issues should be identified by each jurisdiction as a part of its individual smallpox strategy.

Table 7: Isolation locations for small and large outbreaks

	SMALL OUTBREAK	LARGE OUTBREAK
Suspected or Confirmed Initial Case(s)	• Hospital setting for isolation because of potentially small number of cases • Room with negative pressure isolation capability • Room should meet OSHA, JCAHO or Tuberculosis Standards if in hospital • Separate rooms for each patient, if possible • Vaccinate and isolate immediate family members at home • Vaccinate hospital workers in contact with patients	• Recommend non-hospital setting for isolation • Single -family dwelling or other building designated for isolation • No shared ventilation • Controlled access into and out of the isolation area(s) • No cohorted cases, if possible • Adequate amenities (water, electricity, food, etc.) • Vaccinate and isolate immediate family members in household with patients
Confirmed Case(s)	• Isolate at home • Send public health personnel into the field to check individuals • Monitor status via telephone	• SAME AS ABOVE
Suspected Cases Due to Heightened Awareness	• Isolate at home • Send public health personnel into the field to check individuals • Monitor status via telephone	• SAME AS ABOVE
Close Contact (asymptomatic and non-infectious)	• Isolate at home • Send public health personnel into the field to check individuals • Monitor status via telephone	• Isolate at home • Set up centralized, neighborhood medical units to check individuals • Monitor status via telephone
Questionable Contact	• No action necessary unless contact was previously admitted to the hospital	• SAME AS SMALL OUTBREAK

Table 8: Isolation facility criteria

• Separate ventilation/HVAC systems • Internal entrances or ability to control access • Food service capability • Ability to control and separate bio-hazardous waste • Basic amenities – i.e., heat, electricity, water, etc.

5.2 Reasons to Change Isolation Strategy

The success of the isolation options identified by the group will vary with the circumstances of a specific outbreak. The group was therefore asked to identify the factors that would cause them to change their isolation strategy from that of a small outbreak strategy to a large outbreak strategy, and then to modify a large outbreak strategy. The group agreed that the general point at which jurisdictions should shift from a small to a large outbreak strategy would be when hospitals begin to implement emergency or disaster plans. A large outbreak strategy would require modification when a jurisdiction determines that its control measures are not limiting the outbreak effectively. The group identified the factors in Table 9 as potential reasons to change a given isolation strategy.

Table 9: Reasons to change isolation strategy

• No decline in new cases • Unexpected signs of transmission – i.e., to unanticipated locations • Failure of vaccine • Inability to implement control measures • Public unwillingness to comply with control measures

The group also identified additional isolation and control options, applicable to both small and large outbreaks. First, jurisdictions might want to cancel public functions where the smallpox virus has the potential to spread beyond the affected population. These functions could include conferences, conventions, sporting events (schools included), community functions, etc. A jurisdiction might also elect to modify the current vaccination strategy to include a larger population. However, the group agreed that regardless of the strategy employed, the principal indicator that a jurisdiction should modify its isolation strategy is failure to control the spread of the outbreak.

5.3 Effect of Outbreak on Transportation Nodes

During a smallpox outbreak, the virus could potentially spread to other jurisdictions through major transportation nodes such as airports, train and bus stations, and shipping ports. The group was asked to consider whether such nodes should be shut down or whether people should be isolated at these nodes, and it concluded that different approaches should be taken in a small outbreak and a large outbreak.

The group did not advocate closing the major transportation nodes during a small outbreak, because it believed such a drastic step in relation to the scale of the outbreak would only serve to augment panic. Instead, the group recommended increased surveillance at major transportation nodes, including screening all outgoing personnel to ensure that they are not exhibiting symptoms and have not contacted suspected or confirmed cases.

However, the group did recommend closing all major transportation nodes in a large outbreak because the potential that a large number of infected people could spread the virus to unaffected jurisdictions across the country would outweigh the potential panic over the shutdown. Additionally, closing major transportation nodes would prevent people from other jurisdictions from entering the infected area and unknowingly exposing themselves to the smallpox virus.

5.4 Guidance for Individuals Exhibiting Symptoms

Regardless of the size of an outbreak, the group recommended offering similar advice to individuals who think they are exhibiting symptoms of smallpox. Foremost, they recommended that these individuals be advised to stay at home and avoid contact with anyone. The group also recommended that individuals' immediate family remain at home with them in the event that they have been infected as well. Symptomatic individuals should be advised to telephone both their physician and the public health department to make an arrangement for an examination, treatment, and interview. The only difference the group noted between small and large outbreaks was in recommending how and where symptomatic individuals would be examined and treated. In a large outbreak, individuals would be asked come to a centralized neighborhood examination and treatment center instead of having someone visit their home, as noted in the discussion of isolation strategies above.

5.5 Legal Authority and Enforcement of Case and Contact Isolation

The legal foundation for implementing and enforcing smallpox isolation is critical to an effective isolation strategy. A legal representative from the Department of Justice (DOJ) who participated in the group indicated that the legal authority to isolate infectious individuals varies from state to state. Some states have the explicit guidance and authority to execute an isolation plan, and others have very general and vague statutes.

The details of statutes for disease isolation vary from state to state. Therefore, the group identified the general qualifications necessary to provide legal authority for isolation and other control strategies, while still preserving the rights of individuals through due process of law (see Table 10). Some current statutes provide sufficient legal authority, but some require court orders to legally isolate individuals if they refuse to cooperate. Without sufficient legal authority and enforceability, an isolation strategy may be compromised, and additional people may come into contact with a contagious individual. Legislative authority should enable timely due process without jeopardizing public safety.

Table 10: Requirements of legal authority

• Should limit the ability of individuals to move freely or infect others • Should empower public health with the ability to mandate treatment or vaccination • Should limit the ability of individuals to expose themselves • Should enact enforceable legislation • Should enable jurisdictions to appropriate facilities for isolating suspected and confirmed cases • Should contain provisions for meeting the needs of those in isolation (food, water, medical supplies, etc.) • Should contain authority to control the remains of any smallpox fatalities

In addition to having the legal authority to implement an isolation strategy, states must also have the capacity to enforce the isolation of individuals when necessary. The group recommended, however, that jurisdictions **should not attempt to strictly enforce their isolation strategy**, regardless of size and scope. The group believed that any attempt to use a "martial law" approach to enforce an isolation strategy would increase the probability that individuals will try to circumvent the directive. Instead, providing individuals with the option to leave helps convey the message that the authorities have the situation under control, thus increasing the probability that people will follow isolation guidelines. The group recognized that some individuals will leave; however, they will not leave as readily as they would if isolation directives were strictly enforced.

The group also identified other passive enforcement mechanisms that might encourage individuals to comply. First, authorities should inform the population that although they may leave, resources to assist the smallpox victims, including vaccine, will remain in

their jurisdiction. The closure of the major transportation nodes will also make it more difficult for large numbers of people to leave. Finally, the group recommended setting up checkpoints along major transportation arteries to register individuals who leave. Personnel at checkpoints would obtain information about individuals and where they are going, should the authorities need to contact them. The delays that this process would likely cause along major arteries will impel some to take alternate routes, but others may be successfully discouraged from leaving.

Because the group recommended a more passive approach to enforcement, they envisioned a limited role for law enforcement personnel. Providing security was viewed as the primary role for law enforcement personnel in support of isolation activities. Security would be necessary at medical and pharmaceutical sites, for health care and public health personnel, and at the major transportation nodes. The group noted that there would be a need for some law enforcement, but this would occur on a case-by-case basis. Public health personnel may require law enforcement support to detain individuals who would are deemed a significant health threat if these individuals refused to comply with isolation directives. However, the group believed that passive enforcement of isolation strategies should minimize the need for such actions.

5.6 Public Communication

Communication with the affected population and surrounding jurisdictions will be critical to successfully implement the isolation strategy. The group viewed public communication as an opportunity to provide the public with accurate information about the outbreak and the isolation requirements to bolster public confidence and minimize panic. Table 11 identifies the information that will be communicated to the public. In most instances, this applies to both large and small outbreaks. The only difference between responses for the two sizes of outbreaks is when the information should be conveyed. The group believed that public communication should be reactive in nature, rather than proactive, during a small outbreak. The group was concerned that if a jurisdiction convened press conferences and distributed information about a small number of cases, the media may foment panic and increase public concern. Instead, the group recommended providing accurate, complete information in response to media queries when it is necessary to effect control measures.

Conversely, the group believes it is important to proactively disseminate information during a large outbreak because the media will focus heavily on the outbreak and it will be necessary to distribute information to minimize the spread of misinformation and panic. While it is important to be proactive, the group recognizes that the nature and scope of the outbreak will make it difficult, if not impossible, to provide information to the public prior to the media's coverage. In order to get the best information out as soon as possible, the group recommends that jurisdictions develop a media packet of smallpox information as a part of their planning process, before an event occurs.

Table 11: Public communication

How To Communicate	What To Communicate	Who Should Communicate	When To Communicate
• Use broadcast media for critical information (instant dissemination) • Use health networks to contact medical and public health personnel • Provide detailed information to the public and the affected population through - Print media - Reverse 911 - Internet - Hotline • Develop pre-event medical information guides	• Basic event information - Explain what is happening - Describe control measures - Provide vaccine information - Update the public on actions in progress • Basic disease information - Early symptoms - How disease is spread - How many additional cases are expected (general estimate) - How to limit spread - Aggregate case information • Basic isolation information - Stay at home to protect yourself and the public - What to do if you exhibit symptoms • Information to build credibility - Knowledge that there will be more cases - Passive enforcement	• Single spokesperson • Best choice for spokesperson will vary according to jurisdictions, but should be a credible source such as a - Physician - Public health commissioner	• When there is a need to control public activities • In response to inquires • When control measures fail • When there is a large outbreak* * The consensus of the work group was that wide reporting of the incident would be counter-productive during small outbreaks.

5.7 Fatality Management

A final element to isolating smallpox cases will be properly handling fatalities. Because of the infectious nature of smallpox, victims' bodies cannot be handled without special precautions. There are a variety of potential points where improper handling of the remains could infect others, including forensic examination, body collection and transport, and funeral preparation and burial.
The group's first recommendation was to place all smallpox fatalities under the control of the local medical examiner. Doing so would allow a jurisdiction's authorities to regulate the conditions under which family members may acquire the bodies. However, individual jurisdictions will need to evaluate their legal authority to manage such fatalities.

Bodies should be collected and released only by special collection teams that have been vaccinated and have adequate Personal Protective Equipment (PPE). Additionally, bodies should be collected and sealed in airtight body bags that minimize the potential for additional infection. Finally, the group recommended that jurisdictions and family members cremate the bodies in a licensed crematorium to ensure that the virus has been destroyed. If family members have personal or cultural reasons for objecting to cremation, then the bodies can be released in a sealed, airtight vault, but under no circumstances should authorities permit family members to embalm the body or conduct an open casket viewing.

The group also determined after discussion that there are no special requirements for the transportation vehicle for contaminated remains. Rather, precautionary measures should be taken in the packaging the bodies before transport. Placing the bodies in airtight body bags would eliminate the need to make any special transportation vehicle requirements.

Finally, the group recommended only one significant difference between the handling of fatalities in a large outbreak and a small outbreak. In a small outbreak, local mortuary personnel could and should continue to handle the bodies, provided they follow the guidance stated above. In a large outbreak, however, the group believed the number of fatalities would overwhelm the existing mortuary capability. In this case, Disaster Mortuary Operational Response Teams (DMORT) should be mobilized to provide additional support. Although DMORTs are an existing capability, jurisdictions may not be aware that such assets are available to assist them with fatality management in a large outbreak. DMORT support should be requested as part of the Federal response package.

6. COMMUNICABLE DISEASE DECISION TREE

The decision trees for communicable diseases were developed in a series of steps. First the results of the breakout groups were analyzed to find the decisions that were identified by each group, what activities the decision prompted, and the outputs from the activities. These were synthesized into a decision tree format and are presented below. No new decisions were identified by the Medical Surveillance breakout group, but several outputs were identified and are documented in Figure 1. Figure 2 depicts the vaccination decision tree assembled by the breakout group. Two decision trees were developed for the isolation/quarantine focus area. The first, Figure 3, deals with the initial patient, and takes place prior to a confirmed diagnosis of the disease. Figure 4 shows the decision tree for isolation/quarantine once a diagnosis has been confirmed. These modules will later be integrated into the larger decision tree at appropriate points.

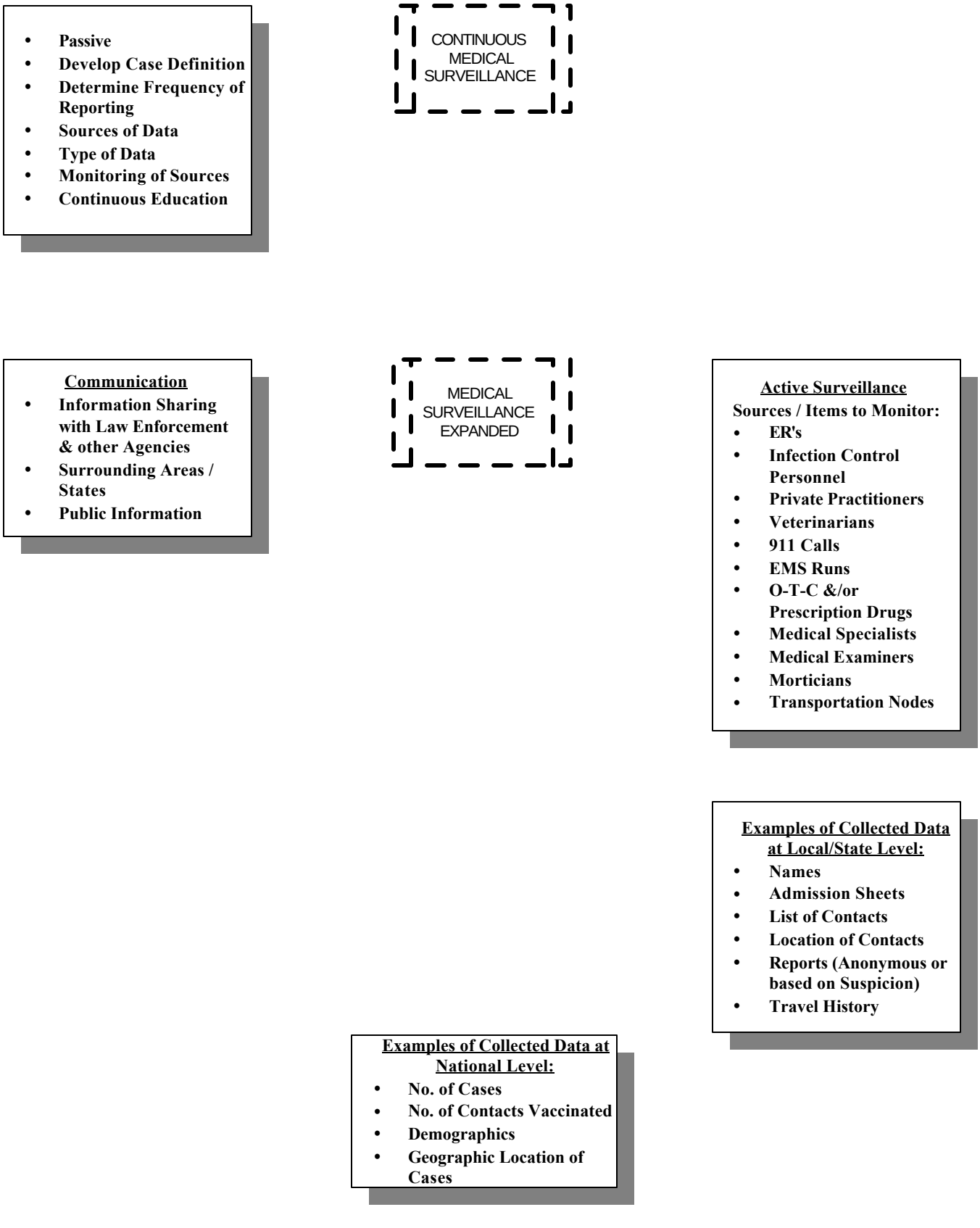

Figure 1. Medical Surveillance

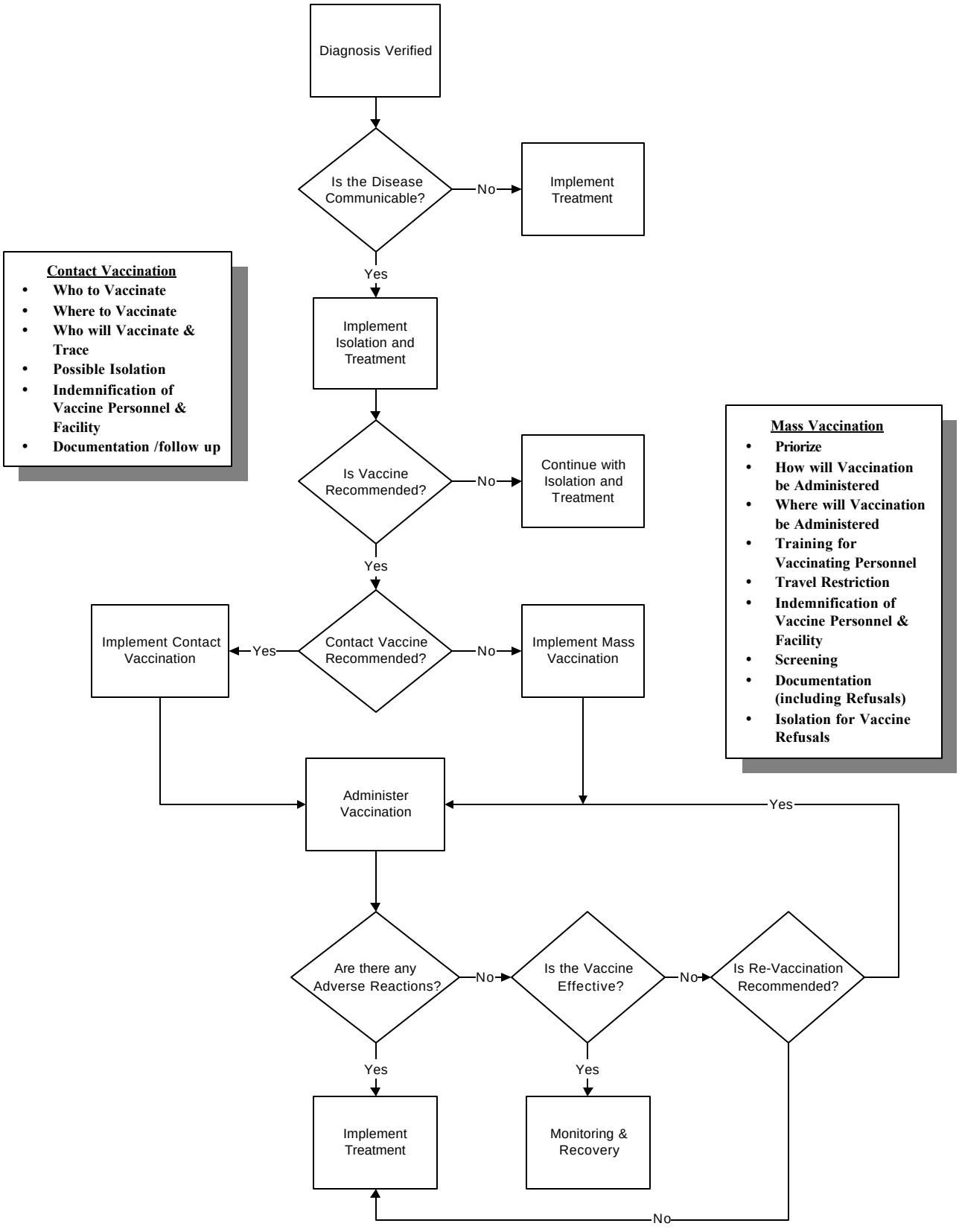

Figure 2. Vaccination

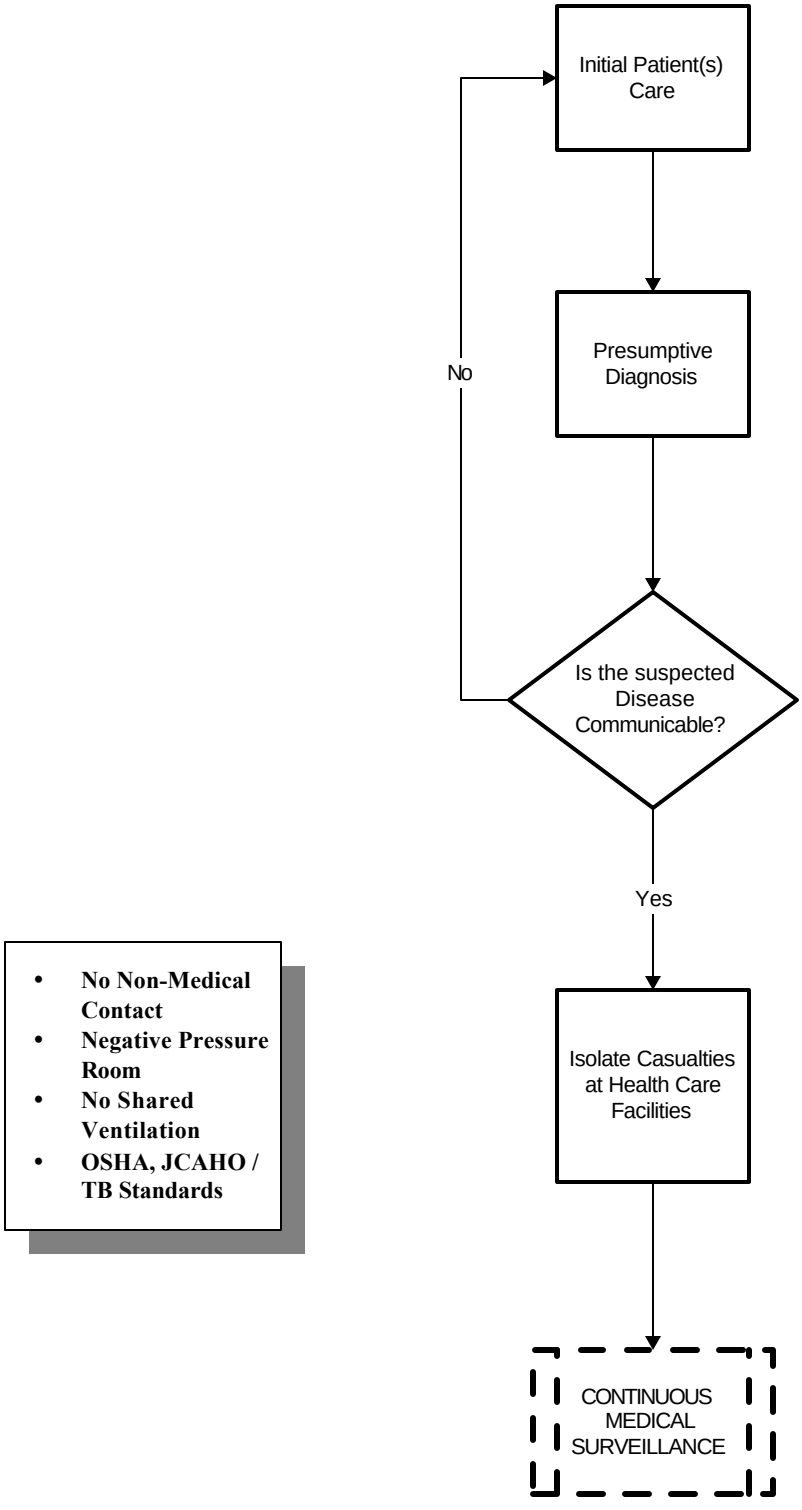

Figure 3. Initial Case Isolation

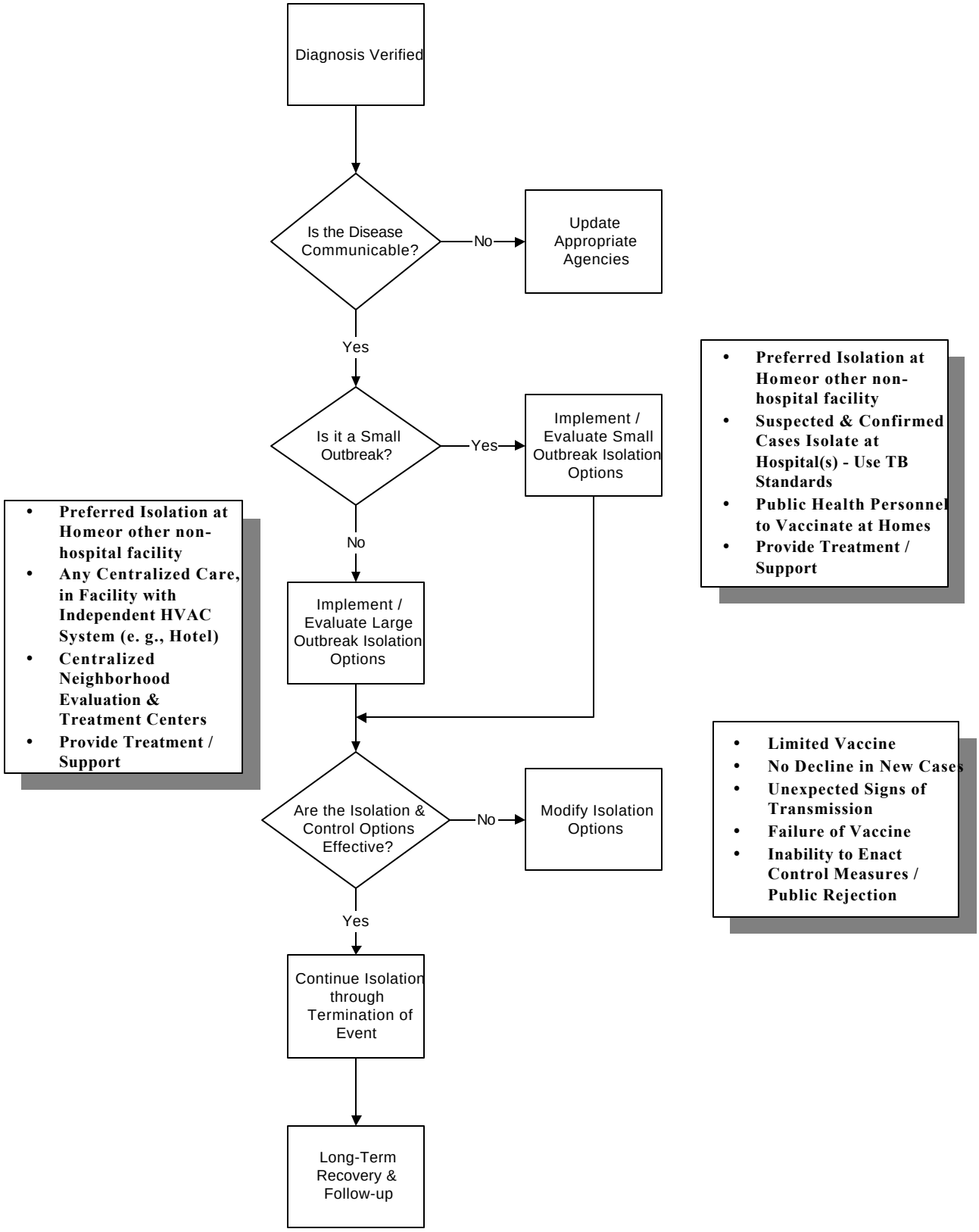

Figure 4. Isolation Upon Confirmation of Diagnosis

7. RESPONSE TEMPLATE

The overriding consequence of a large-scale unannounced BW attack would be the rapid emergence of large numbers of casualties. Response systems need to anticipate and be robust enough to deal with this possibility. A response system should have the expertise to detect and identify a biological agent as early as possible after a release and then be able to institute an existing plan to deal with the onset of casualties in a supportive and non-chaotic manner. Because of the lethal effects of high doses of biological agents, the ability to save many of the casualties exposed to these diseases, even with immediate medical treatment, would be diminished. Therefore, the response systems should also have the capability to deal with high numbers of fatalities. Casualties from an attack on a subway or building could be dispersed widely over metropolitan, multi-state, or multi-national areas. Conversely, a release in a residential area could result in severe incapacitation of entire apartment complexes within one geographic location.

A large-scale BW attack would result in no less than a catastrophic medical emergency. Such an emergency would quickly saturate local emergency response and medical assets unless plans to cope with such an incident are in place in advance of crisis. At this time, such plans do not exist for most cities. The mission of the BW IRP is to find effective strategies for cities to consider when developing response plans for a BW attack that can be integrated across state and federal levels.

The BW IRP team identified the need for a generic BW Response Template and proceeded to formulate one that embodies the concepts and the specific activities that a city could perform to respond effectively to a BW incident. The list of activities that would need to be performed to respond to a major BW terrorist incident is organized into groups that we refer to as components of the response template. Together the components form an integrated response system. The team developed timelines for each response activity to determine how the activities could work together, in different attack scenarios, to deal with the dynamics of the onset of casualties. The team then analyzed the personnel and material resources needed to perform each response activity. Lastly, the team estimated the sources and timing of personnel resources from local, state, and federal assets to determine the overall practicality of the response template and identify shortfalls.

The template may be used as a starting point for formulating local plans and protocols and preparing to respond to a BW incident. Based on the discussions and results from the breakout groups, modifications were proposed for the response template that were unique to a bioterrorist event involving a communicable disease.

The recommended changes are summarized below. See Appendix G for the original components and the recommended changes of each response template module.

Continuous Surveillance
Add school absences and increase in reportable diseases to the possible indicators to monitor.

Expanded Surveillance
Add "poll pharmaceutical distribution points" to the active data collection items. Note, this particular item may be of use in some communicable diseases, but would not provide much useful data for smallpox.

Medical Diagnosis Activities
No changes were recommended.

Epidemiological Investigation Activities
Add “contact-tracing” to the information-gathering efforts.

Criminal Investigation Activities
Add the new major activity “Implement protective measures for investigators.”

Local Command and Control Activities
Add the new major activity “Request state disaster declaration.”

State Command and Control Activities
In the activity dealing with activation of the National Guard, delete the word “companies.”

Federal Command and Control Activities
Add a new major activity, “Deploy Federal medical assets.”

Residual Hazard Mitigation & Control Activities
Add a new major activity: “Conduct control measures and decontamination at facilities and sites, as appropriate.”

Activity 6: add “law enforcement” as a group to which equipment and personnel should be provided.

Mass Prophylaxis Activities
Change title to **“Immunization and Prophylaxis”**

Add major activities: “Immunization at community centers, homes and other places (as determined)”, “Arrange for security, as required”, and “Control critical pharmaceuticals.”

Care of Casualties Activities
Delete the subactivity “Admit casualties until hospitals are full” under “Provide care to initial patients” and replace with “Admit patients until best treatment facilities are determined.”

In second activity, change “Emergency Medical System” to "Modular Emergency Medical System.”

In third activity, add “subordinate” prior to “medical command.”

In the fifth activity, “Establish casualties collection sites to assess and triage casualties (e.g., NEHC),” add “…, as required.”

At the end of the first sub-activity, “Provide triage to separate worried well from acutely ill”, add “…or infectious patient.” Add “hotel” to possible sites.

In seventh activity, after “Establish community outreach,” add parenthetic phrase “(Particularly important for communicable diseases)”
Change sub-activity 3 to “Distribute medication/administer vaccine and self help instructions.”

Add sub-activity “Initial contact tracing”

Add major activities: "Implement protective measures for health care personnel” and "Establish and initiate infection control measures, as needed:

-Education and infection control
-Minimize public gatherings
-Immunize, prophylaxis, limit contact to control spread
-Closing schools—immunize face-to-face contacts
-Isolation, quarantine, etc. to minimize spread of infection
-Use of personal protective apparel
-Minimize exposure (by use of above) and disinfection, disposal, and hand washing techniques

Control of Affected Area & Affected Population Activities

In second activity, add new sub-activity “Limit public gatherings, e.g., close schools, sporting events, etc.”

In third activity, add new sub-activities “Limit mass transportation (for communicable diseases) e.g. air terminals, rail heads, bus terminals, etc." and “Do not prohibit individual travel, but obtain tracking information."

In fifth activity, add sub-activities “Health care facilities” and “Pharmaceutical storage sites”

In eleventh activity, replace “Emergency Broadcast System” with “Emergency Alert System.”

In thirteenth activity, replace “Joint Information Center (JIC)” with “Central Information Center.”

Resource & Logistic Support Activities
In the eighth activity, add "…and to home isolated victims."

Fatality Management Activities
In seventh activity, change second sub-activity to, "Conduct burial (sealed container mandatory for communicable disease)" and change third sub activity to "Conduct cremation (preferred for communicable disease)."

Continuity of Infrastructure Activities
In seventh activity, delete "command" and add "…including protective measures."

Family Support Services Activities
No changes.

APPENDIX A

AGENDA

CDC/DOD SMALLPOX WORKSHOP
AGENDA

17 April 2000

8:00	Registration	
8:30	Introduction	DeZearn/Rotz
8:45	History/Background BWIRP	Mughal
9:15	Decision Tree	DeZearn
9:45	CDC Initiatives/Vaccine Stockpile	Dotson
10:15	Break	
10:30	Smallpox 101	Lane
11:00	CDC Smallpox Strategy	Rotz
12:00	Lunch	
1:00	Smallpox Scenario	Lowry
1:15	Instruction to Breakout Groups	Rotz/DeZearn
1:30	Breakout Groups 1. Vaccination Strategies (Contact Vaccination) 2. Medical Surveillance (State/Local) 3. Isolation/Quarantine (Small Number of Cases)	
5:00	End of Day	

18 April 00

8:30	Breakout Groups (Cont.) 1 Vaccination Strategies (Contact Vaccination) 2 Medical Surveillance (State/Local) 3 Isolation/Quarantine (Small Number of Cases)	
10:00	Break	
10:15	Report on Breakout Groups (Day 1)	
12:00	Lunch	
1:00	Breakout Groups 1 Vaccination Strategies (Expanded Vaccination) 2 Medical Surveillance (National) 3 Isolation/Quarantine Issues (Large Number of Cases)	
5:00	End of Day	

19 April 00

8:30	Report on Breakout Groups, Day 2	
10:30	Instructions for Decision Tree Breakouts	DeZearn/Crawford
10:45	Break	
11:00	Breakout Groups (Decision Tree) 1 Quarantine 2 Medical Surveillance 3 Vaccination	
12:00	Lunch	
1:00	Breakout Groups (Decision Tree) (Cont.) 1 Quarantine 2 Medical Surveillance 3 Vaccination	
2:00	Assembly of Decision Tree	DeZearn/Crawford
3:00	Break	
3:15	Template Validation	DeZearn/Crawford
4:30	Wrap-up	
5:00	End of Day	

APPENDIX B

WORKSHOP ATTENDEES

Attendees
CDC/DOD Smallpox Workshop
April 17-19, 2000

Name	Organization	Address	E-mail	Phone
1. Ayala, Eddie	Battelle	2012 Tollgate Road, Suite 206 Bel Air, MD 21015	ayala@battelle.org	(410) 569-0200 (410) 569-0588 (f)
2. Bailey, Charles	Battelle – Medical	7501 Memorial Parkway South Ste. 101 Huntsville, AL 35802	Baileyc@battelle.org	(256) 705-1355 (256) 883-4442 (f)
3. Bell, Michael	Centers for Disease Control National Center for Infectious Diseases	Hospital Infections Program National Center for Infectious Diseases Centers for Disease Control and Prevention 1600 Clifton Road, N.E. MS A-35 Atlanta, GA 30333	Zzb8@cdc.gov	(404) 639-6490 (404) 639-2647 (f)
4. Bice, Steven	Centers for Disease Control National Center for Environmental Health	Director, National Pharmaceutical Stockpile Program National Center for Environmental Health Centers for Disease Control & Prevention 4770 Buford Hwy, N.E., MS F-23 Atlanta, GA 30333	sgb3@cdc.gov	(770) 488-7516
5. Blackman, Ed	RPI	Research Planning, Inc. Bldg. E5307 Hoadley Road APG, MD 21010	Edward.Blackburn@sbccom.apgea.army.mil	(410) 436-7980

Attendees
CDC/DOD Smallpox Workshop
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Name	Organization	Address	E-mail	Phone
6. Bowlus, Rick	CHPPM—Risk Communication	US Army Center for Health Promotion and Preventive Medicine ATTN: MCHB-TS-EHR (Bldg. 1675) APG, MD 21010	Rick.Bowlus@apg.amedd.army.mil	(410) 436-5208/ 7715 (410) 436-8170 (fax)
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9. Church, Jim	SBCCOM	5183 Blackhawk Road APG, MD 21010	James.church@sbccom.apgea.army.mil	(410) 436-5686
10. Crawford, Chuck	SBCCOM	5183 Blackhawk Road APG, MD 21010	Chuck.crawford@sbccom.apgea.army.mil	(410) 436-3640
11. Dembek, Zygmunt Dr.	CT Dept. of Public Health	Epidemiology Program Connecticut Dept. of Public Health 410 Capitol Avenue, MS#11EPI P. O. Box 340308 Hartford, CT 06134-0308	zygmunt.dembek@po.state.ct.us	(860) 509-7994 (860) 509-7910 (f)
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13. Dixon, Timothy	Battelle	2012 Tollgate Road, Suite 206 Bel Air, MD 21015	dixont@battelle.org	(410) 569-0200 (410) 569-0588 (f)
14. Dotson, Debra	CDC – Bioterrorism Response & Preparedness	Bioterrorism Preparedness & Response 1600 Clifton Road, N.E. Mailstop C-18 Atlanta, GA 30333	dnd6@cdc.gov	(404) 639-0398

Attendees
CDC/DOD Smallpox Workshop
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Name	Organization	Address	E-mail	Phone
15. Dragunsas, Gint	Booz-Allen	1309R-Continental Drive Abingdon, Md 21009	dragunas_gint@bab.com	(410) 436-7244
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17. Franck, Janet N.	Association of Professionals in Infection Control & Epidemiology	1131 Dunwoody Dr. St. Louis, Missouri 63122	Jnauf@aol.com	(314)-909-1567 (f) (314) 424-4422 (beeper)
18. Gaydos, Joel Dr.	HM Jackson Foundation DoD Emerging Infections	WRAIR, Walter Reed 503 Robert Grant Avenue Silver Spring, MD 20910-7500	Joel.Gaydos@na.amedd.army.mil	(301) 319-9112 (301) 319-9213 (f)
19. Helfrich, Richard	Montgomery Co. Public Health	Montgomery Co. Public Health 1301 Piccard Drive, Ste. 4200 Rockville, MD 20850	Helfrr@co.mo.md.us	(240) 777-4251
20. Henderson, D.A., Dr.	Center for Civilian Biodefense Studies	111 Market Place, Suite 850 Baltimore, MD 21202-6709	Dahzero@aol.com	(410) 223-1667 Fax (410) 223-1665
21. Jarboe, Ted	Montgomery Co. Fire & Rescue Service	Montgomery Co. Fire & Rescue Service EOB, 12th Floor 101 Monroe Street Rockville, MD 20850	Ted.jarboe@co.mo.md.us	(240) 777-2493 777-2415 (f)
22. Johns, Malcolm	U.S. Public Health Service	Office of Emergency Preparedness, National Disaster Medical System, 12300 Twinbrook Parkway, Suite 360, Rockville, MD 20857	Mjohns@osophs.dhhs.gov	(301) 443-3499
23. Kortepeter, Mark Major	USAMRIID	Medical Operations Division 1425 Porter Street Ft. Detrick, MD 21702-5011	Mark.kortepeter@det.amedd.army.mil	(301) 619-4994 (301) 619-2312 (f)

Attendees
CDC/DOD Smallpox Workshop
April 17-19, 2000

Name	Organization	Address	E-mail	Phone
24. Kotras, Diane Ms.	OSD-SOLIC	1410 North Scott Street #969 Arlington, VA 22209	dmkotras@prodigy.net	(703) 695-0190 (703) 693-2578(f)
25. Kuker, Kathleen	FBI – WMD Operations Unit	Weapons of Mass Destruction Operations Unit 935 Pennsylvania Avenue, NW Rm. 11741 Washington, DC 20535	Kkuker@leo.gov	(202) 324-0259 (202) 324-6928 (202) 324-8649 (fax)
26. Kussman, Richard	Battelle	2012 Tollgate Road, Suite 206 Bel Air, MD 21015	Kussmanr@battelle.org	(410) 569-0200 (410) 569-0588 (f)
27. Lane, Michael J. Dr.	Department of Family and Preventive Medicine	869 Cliffton Road, NE Atlanta GA 30307-1223	Mlane@fpm.eushc.org	404-686-7634
28. Lowry, Peter.	Battelle	2012 Tollgate Road, Suite 206 Bel Air, MD 21015	lowryp@battelle.org or peterhlowry@erols.com	(410) 569-0200 (410) 569-0588 (f)
29. Lumpkins, Don	Maryland Emergency Management Agency	State Emergency Operations Center, 5401 Rue Saint Lo Drive, Reisterstown, MD 21136	Dlumpkins@mema.state.md.us	(410) 517-3600
30. McGovern, Clement	Department of Justice	601 D Street, N.W. Suite 6500 Washington, DC 20530	Clement.mcgovern@usdoj.gov	(202) 305-0535 (202)574-8714 (f)
31. Mrozinski, Greg	SBCCOM	5183 Blackhawk Road APG, MD 21010	Gregory.mrozinsk@sbccom.apgea.army.mil	(410) 436-2963
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33. Olshack, David	FBI – NDPO	FBI Headquarters Room 11286 935 Pennsylvania Avenue, NW Washington, DC 20535	dolshack@leo.gov	(202) 324-0276
34. Perkins, Philip H.	Battelle	2012 Tollgate Road, Suite 206 Bel Air, MD 21015	Perkinsp@battelle.org	(410) 569-0200 (410) 569-0588(fax)

Attendees
CDC/DOD Smallpox Workshop
April 17-19, 2000

Name	Organization	Address	E-mail	Phone
35. Rotz, Lisa	CDC – Bioterrorism Response & Preparedness	Bioterrorism Preparedness & Response 1600 Clifton Road, N.E. Mailstop E-51 Atlanta, GA 30333	Ler8@cdc.gov	(404) 639-0153
36. Socher, Myra	TriMed, Inc. (Hospital)	1916 Wilson Boulevard Suite 300 Arlington, VA 22201-3037	Trimed@nsainc.com	(703) 524-7780
37. Stiner, Scott Lieutenant	Pinellas County Sheriff's Office	P.O. Box 2500 10750 Ulmerton Road Largo, FL 33779	rstiner@co.pinellas.fl.us	(727) 582-6486
38. Wall, Joel Lieutenant Colonel	US Army DOMS - WMD Domestic Preparedness Branch	DOMS (DAMO-ODS) ATTN: WMD Domestic Preparedness 400 Army Pentagon, RM BF763A Washington, DC 20310-0400	Joel.wall@doms.army.mil	(703) 695-1288

APPENDIX C

INFORMATION BRIEFINGS

Domestic *Preparedness*

Domestic Preparedness to Biological Terrorism and the Interagency, Intergovernmental Biological Weapons Improved Response Program

Dr. Mohamed Mughal
U.S. Army SBCCOM

April 17, 2000

Agenda

- Nunn-Lugar-Domenici
- BW IRP
  - Process
  - BW Response Template
  - Conclusion & Future Plans

Domestic ***Preparedness***

Purpose of Nunn-Lugar-Domenici

- To provide enhanced support to *improve the capabilities of state and local* emergency response agencies to prevent and respond to terrorist incidents involving weapons of mass destruction at both the national and local levels

- To enhance the capability of the Federal Government to *prevent and respond* to such events

Improved Response Process

Enhance Responder Actions through Systematic Analysis of Concepts, Plans, Procedures and Equipment

Process

- BW IRP is
  - A multi-year effort
  - A multi-agency team
- BW IRP began April 1998 and has
  - completed an assessment of the BW response problem
  - formulated an integrated approach to BW emergency response
  - identified gaps and improvements in response capabilities

Process (cont.)

- A team of over 60 Federal, State and local responders and technical experts drawn from nine states around our nation
- The process:
  - provided a forum to educate and inform
  - produced and continuously refined an initial integrated BW response template
  - identified and prioritized shortfalls
  - identified response improvement concepts

Process (cont.)

- Series of five three-day workshops
- Day 1 - tutorials / pre-selected topics
- Day 2 - presentation of a selected BW terrorist attack scenario / developed response activities designed to mitigate the emerging consequences of the scenario
- Day 3 - reviewed and integrated the response template

Process Evolution

- Process did not remain static
- Format for scenarios / response template
- Scenario in a temporal format
- Categorized casualties into the phases of each disease and identified the daily numbers of casualties in each phase of the disease

Process Evolution (cont.)

- Develop our response activities in chronological order
- Integrated set of response activities became response template
- Organized response template into a work breakdown structure of major types of activities

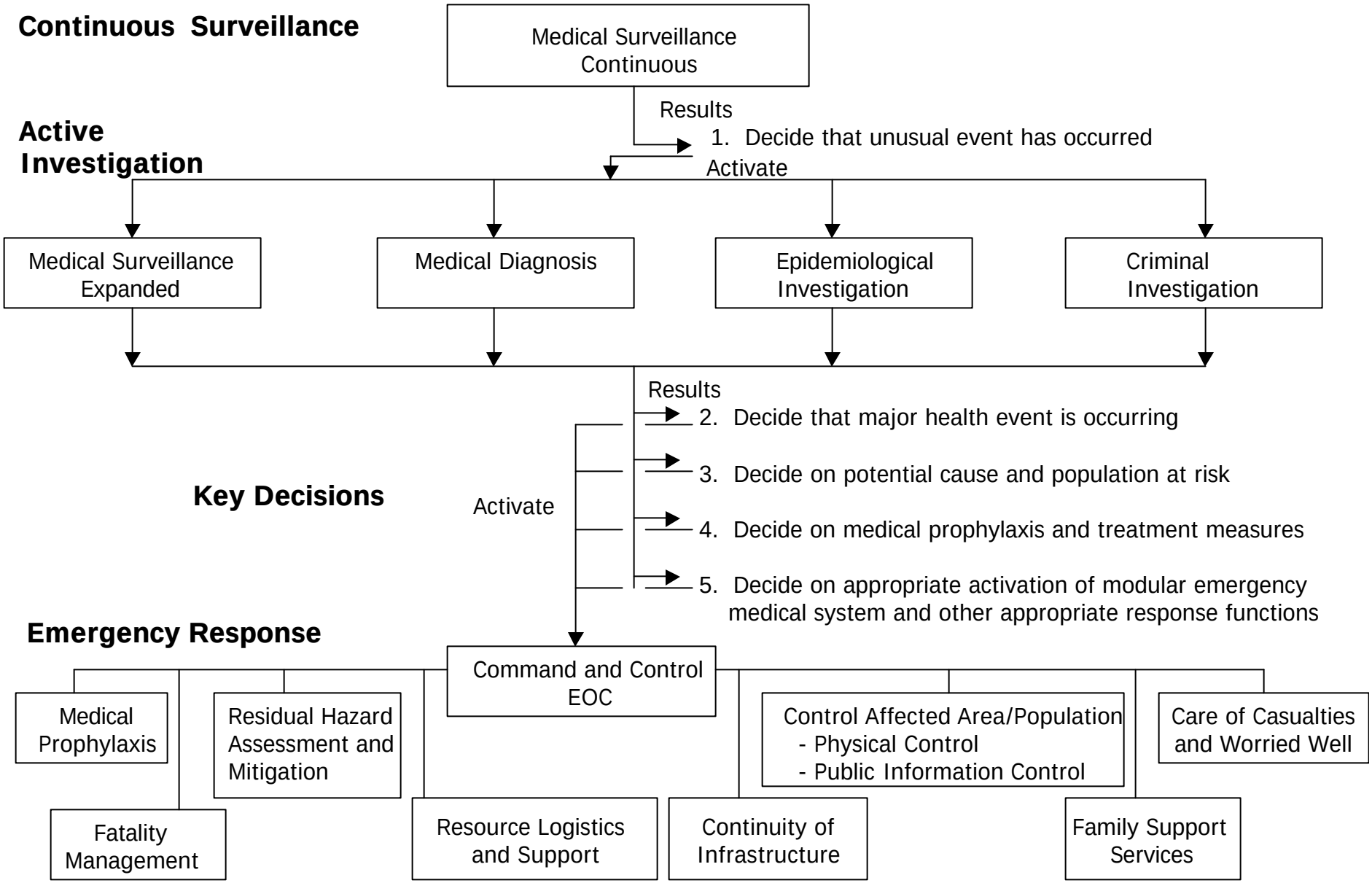
Attack Scenario

- 5 potential BW scenarios were analyzed (covert release of BW agent)
  - Scenario #1: Tularemia producing 1,100 casualties
  - Scenario #2: Staphylococcus Enterotoxin B in combination with Tularemia producing 22,500 casualties, of which 10,000 were fatalities

Attack Scenario (cont.)

- Scenario #3: *Bacillus anthracis* spores producing 126,000 casualties, of which 120,000 were fatalities
- Scenario #4: Venezuelan Equine Encephalitis (VEE) producing 1,300,000 casualties, of which 13,000 were fatalities
- Scenario #5: Rift Valley Fever on a cattle feed lot infecting 700,000 cattle and producing 48,000 human casualties, of which 250 were fatalities

BW Response Template Components and Key Decisions



Key BW Consequences

- Dynamics of onset of casualties
- Dosage of agent
- Geographic dispersion of casualties
- Scene of attack
- Residual hazard

Considering the Whole Problem

- Timing of response is the key
  - Surveillance to detect attack
  - Make response decisions quickly
  - Implement pre-existing response plans
  - Distribute prophylaxis (if applicable) quickly
  - Keep up with flow of sick and worried well
  - Establish system to receive and rapidly utilize outside help

Conclusions

- A BW terrorist event would primarily represent a public health *catastrophic medical emergency*
- An organized, effective emergency response to a large BW attack involving a million or more people appears possible
- BW response must be led by local community
- Manage existing resources, plan BW response and improve surveillance - modest cost

Domestic *Preparedness*

Conclusions (cont.)

- The most crucial aspect of an effective total response system will be the medical response - need medical community buy in and participation
- City officials will need to make difficult decisions on a presumptive basis
- Physical and public information control necessary

Conclusions (cont.)

- Timely and effective medical response to a large number of BW casualties would require the rapid establishment of:
  - Neighborhood Emergency Help Centers to receive casualties and worried well, provide triage, dispense pharmaceuticals and instructions
  - Acute Care Centers to provide definitive and supportive care to the critically ill
  - Sector outreach to provide instructions, pharmaceuticals and mobilization of citizen self-help for the critically ill that stay at home

Conclusions (cont.)

- Need State, regional and Federal assets for BW incident
- Response strengthened if cities adopted similar emergency medical modules and response strategy
- Prevention measures also important - protecting buildings and immediate detection of attacks
- Need to consider long-term effects, distributed attacks and agricultural targets

CDC's Smallpox Initiatives

Debra A. Dotson, R.Ph.

Bioterrorism Preparedness and Response Program

National Center for Infectious Diseases

Objectives

- Current Smallpox Vaccine
- Additional Smallpox Vaccine
- Research

Current Smallpox Vaccine

- Needles
  - Procurement
- Diluent
  - Procurement
  - Contingency
- NIH Dilutional Study
  - St. Louis University
  - 60 subjects
  - 3 arms

Request for Proposal- Additional Smallpox Vaccine

- Commerce Business Daily- January 27, 2000
  - Candidate smallpox vaccine using vaccinia cell culture
  - Pilot lot
  - FDA approved BLA
  - Manufacture bifurcated needles
  - Formulate and produce diluent
  - Manufacture & ship/store to maintain 40 million dose stockpile (new and in-date vaccine)

Request for Proposal- Additional Smallpox Vaccine

- Objective of RFP:
  - "…is to achieve FDA licensure and initiate large-scale production of a new vaccine in the shortest time possible."

Timeline for RFP ✍ Contract

- Responses to RFP- February 11, 2000
- Panel Review of RFPs- April 24-28, 2000
- Tentative Contract Award Date- July 1, 2000

Smallpox Research

- Current CDC research activities
- Monoclonal antibodies
- Antivirals

Other Activities

- Revised 1970 Smallpox Plan
- Advisory Committee for Immunization Practices (ACIP)
- VIG requirement estimations and acquisition strategies

Smallpox Overview

J. Michael Lane, MD, MPH

Smallpox transmission -1

- Statements about transmission must be interpreted with caution because studies of transmission occurred in populations 40% to 75% immune from vaccination or prior smallpox

Smallpox transmission -2

- Smallpox is much less infectious than measles
  - median age
  - lower attack rates in exposed susceptibles
  - longer time to exhaust susceptibles
  - small populations capable of sustaining transmission

Smallpox transmission -3

- Transmission occurs largely via prolonged face-to-face contact
  - fomite transmission occurs but is rare
  - airborne transmission occurs but is rare
  - transmission has been documented from dead bodies

Smallpox transmission -4

- The vast majority of transmission occurs from one day before to 5 or 6 days after the skin rash becomes prominent

Smallpox transmission -5

- In "natural" transmission, each case causes 1 to 3 new cases during periods of low heat and humidity, or 0 to 0.9 cases in periods of high heat and humidity

Smallpox transmission -6

"Hyper spreaders" are rare but occur. These can yield 6 to 23 cases in the next generation

Smallpox transmission -7

- Hemorrhagic cases can be hyper spreaders, but because of prostration and rapid death, this is rare

Smallpox transmission -8

- Good studies of V. major in the Indian subcontinent showed that:
  - 36% to 88% of unvaccinated household contacts with prolonged intimate exposure develop disease
  - each case results in 0 to 3 new cases
  - population attack rates were about 180/100,000/year in unvaccinated persons
  - the vast majority of spread was to close household contacts
  - transmission was very low in hot wet months

Smallpox transmission -9

- Transmission has not occurred on a common carrier (train, bus, taxi, airplane etc.) despite several anecdotes about long trips on such carriers during theoretically infectious periods

Smallpox transmission -10

- Study of importation outbreaks in Europe revealed:
  - 49 outbreaks, 13 with no spread
  - average of 15 cases and 3 deaths per outbreak
  - most transmission occurred within hospitals
  - background population immunity probably was less important in terminating outbreaks than was the public health response

Smallpox transmission -11

- Expanding ring vaccination (about 5 to 200 vaccinations per case) should terminate outbreaks rapidly
- Isolate cases
- Avoid hospitalization if possible

Smallpox transmission -12

- "It is my judgment that under contemporary conditions smallpox cannot be said to live up to its reputation. Far from being a quick-footed menace, it has appeared as a plodding nuisance with more bark than bite."
  - Tom Mack, Smallpox in Europe, J. Infectious Diseases 1972

Basic clinical smallpox -2

- When a non-immune person inhales viral particles, they settle and reproduce in the upper respiratory tract

Basic clinical smallpox

- Smallpox is a viral disease spread from person to person via the respiratory route. There is no non-human reservoir

Basic clinical smallpox -3

- About 5 or 6 days after inhalation, the cells in which the virus has been replicating release large amounts of virus into the bloodstream, resulting in a primary viremia. The virus is cleared from the bloodstream by the reticulo-endothelial system.

Basic clinical smallpox -4

- About 12 days after the original inhalation, there is a massive secondary viremia, which produces fever and intense malaise. The virus settles in many organs, including the skin and upper respiratory tract.

Basic clinical smallpox -5

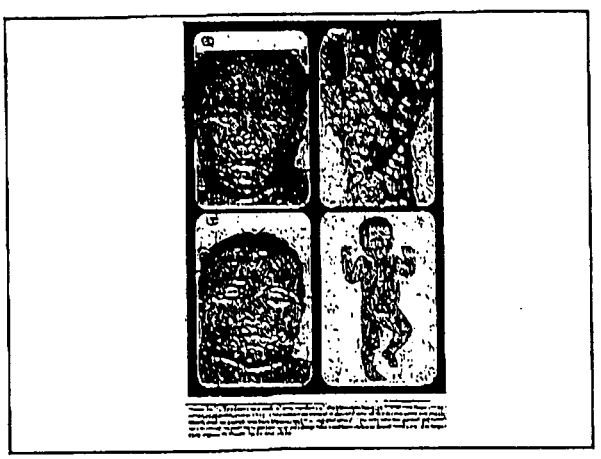
- About 14 days after inhalation, a fine macular rash appears on the skin, in the mouth, and throat. The patient is maximally infectious to others via respiratory secretions from about the 13th to about the 20th days after infection.

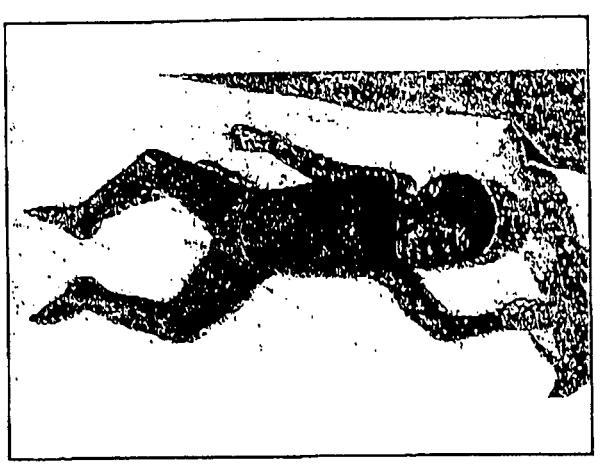
Basic clinical smallpox - types

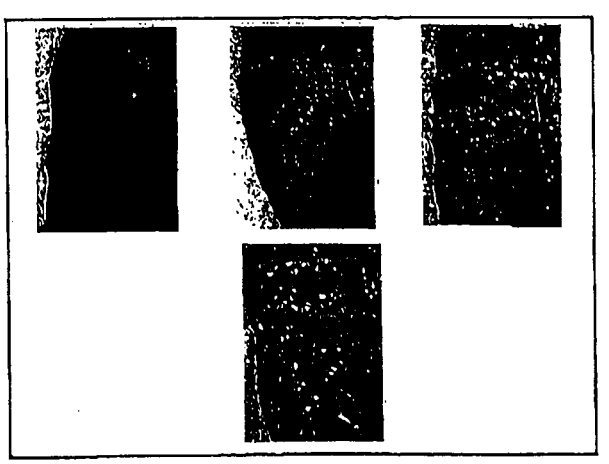
- Ordinary (most common)
- Modified
- Flat
- Hemorrhagic

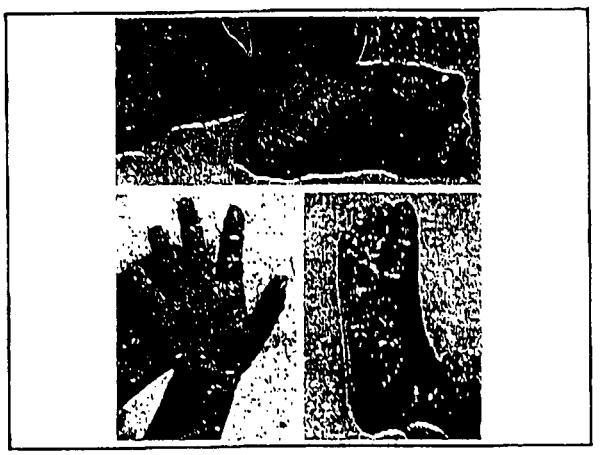
Basic clinical smallpox -6

- The rash evolves in a characteristic way, becoming papular, pustular, and often somewhat confluent. The patient is very sick. Scabs begin to form around the 7th or 8th day after the rash appears, and the patient begins to recover.









Basic clinical smallpox -8

- While scabs contain infectious viral particles, transmission during the scabbing, healing phase is uncommon.

Basic clinical smallpox -7

- Most deaths occur during the first week of the rash. Death can be via massive cardiovascular collapse, from secondary infection, from encephalitis, and other complications.

Basic clinical smallpox -9

- By about 2 weeks after the onset of the rash, patients are either dead or well recovered and immune.

Basic clinical smallpox -10

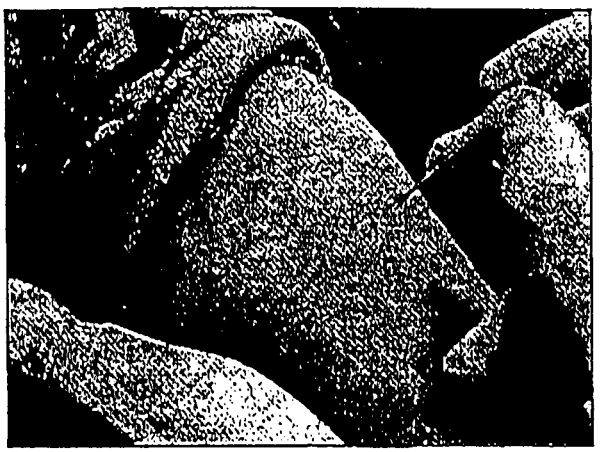
- About 1% to 3% of cases of V. major in non-immune persons become hemorrhagic, often before the rash has developed in a characteristic fashion. These patients usually die, and probably represent disseminated intravascular coagulation
- Flat-type also rare form of disease

Basic clinical smallpox -11

- The death rate is about 30% to 40%, higher in very young children and pregnant women.

Basic clinical smallpox -12

- In skilled hands, material taken from the pustules yields large amounts of virus, which can be identified by electron microscope, or by growing the virus on embryonated chicken eggs.



Smallpox: Current Vaccine

- Made from vaccinia virus -- related pox virus
- Intradermal inoculation with bifurcated needle (scarification)
- Vaccination 2 or 3 days after exposure to smallpox generally will abort the infection.

WHO: Smallpox vaccine vials

Vaccination against smallpox -5

- Complications are rare, but vaccination involves infection with a live pathogenic virus, and complications are frequent enough to avoid indiscriminate mass vaccination.

Vaccination against smallpox -7

Complications per million adult primary vaccinees

Complication	Number
Post vaccinial encephalitis	4
Vaccinia necrosum	7(*)
Eczema vaccinatum	30
Accidental inoculations	200+
Generalized vaccinia and various rashes	600+
Fetal wastage	?
Death	est. 3 Or 4

(*) may be higher in HIV/AIDS era

QUESTIONS?

CDC Smallpox Strategy

Lisa Rotz, MD

This Briefing omitted at request of briefer

APPENDIX D

WORKSHOP SCENARIO

SMALLPOX SCENARIO

During late 1999, the 30th of February Anti-Zionist Movement, a terrorist group, acquires a small amount of smallpox virus. They obtain it through the Russian Mafia from former Soviet weapons stock. Their intent is to conduct a "demonstration" of their resolve and capability by causing a smallpox outbreak in the United States. They anticipate the smallpox outbreak will be contained. However, in the period after the attack--but before the US can begin to create more supplies of vaccine--they intend to demand that the US substantially alter its Middle East policy. If their demands are not met they plan to stage a larger attack.

In April 2000, the container of virus is smuggled across the boarder, overland from Mexico. It is released on April 15th aboard Fat Chance Airlines flight 007, a commercial aircraft going from Dallas to Cincinnati, with a stop in Little Rock, Arkansas. A female terrorist sprays the virus from a container disguised as a perfume bottle. It spreads throughout the aircraft via the recirculated air and infects 83 of the people on the aircraft. The terrorist, who has been vaccinated, flies on to Frankfurt Germany, where she changes identities and then returns to the terrorist's base in the Republic of Extremistan.

Within 13 days the first cases show up in Little Rock, the Greater Cincinnati area, and Chicago where the flight crew is based. Fifteen people are infected in Little Rock, 62 in the Greater Cincinnati area (which includes eastern Indiana and northern Kentucky, and 6 (two pilots and 4 flight attendants) in Chicago. Because of the time of day, and the fact that the flight is not non stop, the Cincinnati passengers are terminating in that area rather than going on. The Cincinnati passengers are distributed In the Greater Cincinnati area as follows:

1. 19 on the east side of Cincinnati.
2. 7 downtown.
3. 3 in Amberly village.
4. 10 on the West Side of Cincinnati.

5. 10 in northern Kentucky (Covington and Newport).
6. 2 in Dayton.
7. 2 in Lexington KY.
8. 1 in Brown County Ohio.
9. 3 in Indianapolis.
10. 2 in Shelbyville Indiana.
11. 2 in Louisville KY.
12. 1 in Maysville KY;

With the exceptions of 3 students in Clifton at the University of Cincinnati, and one man in Georgetown Ohio, all use a primary care doctor.

On April 27th, Patient A presents to the emergency room at the Hospital in Georgetown Ohio with high fever (102-103) chills, headache, dorsal and lumbar back pain and general prostration. A complete blood count (CBC) does not show an increased number of white cells or a "left shift" but a mild leukopenia. He is diagnosed with flu and sent home. On the same day, Patient B presents with similar symptoms to student health at the University of Cincinnati. Patient C sees his Physician in Little Rock with similar symptoms, but also with some nausea and vomiting, as does Patient D in Blue Ash, a Cincinnati suburb. All are diagnosed with flu or viral syndrome.

In Shelbyville Indiana, Little Rock, and the Greater Cincinnati area 20 people develop similar symptoms but do not seek medical care and self treat.

In Chicago on April 28th both pilots are seen by the flight surgeon that takes them off flying status. Again the presumptive diagnosis is flu. In Louisville Kentucky, Little Rock, Indianapolis, and the Greater Cincinnati area 51 people develop similar symptoms but do not seek medical care and self treat.

On April 29th the remainder of the infected on the plane are having flu like symptoms; those who developed symptoms on the 27th are beginning to develop a rash.

On May 1st, patient A returns to the hospital. The fever has subsided and the rash has become pustular. When he appears at the intake desk the triage nurse quickly takes him to an isolation room; the illness is diagnosed as chicken pox and the patient is again sent home. Patient B is similarly diagnosed with chicken pox at student health but is admitted to hospital and given an isolation bed rather than being sent back to the dormitory.

On May 2d, in Chicago, the flight surgeon who is following the pilot and copilot sees both of them with a pustular rash. When both of them give a firm history of childhood chicken pox, she becomes concerned and sends specimens to a lab to rule out varicella (Chicken Pox). She checks on the cabin attendants and on learning that they have similar symptoms calls the Chicago public health department. After confirming laboratory results and seeing the two pilots, the Public Health Physician calls the CDC at about 1 PM. The college student in the University Hospital is seen on rounds by the Chief of Infectious Disease who observes the centripetal pattern of the pustules and their presence on the soles of feet and palm of the hands and notes the students history of childhood chickenpox. Laboratory testing to rule out varicella is also ordered. When that result is negative the physician calls both the Cincinnati Health Department and the CDC. This phone call comes about one hour after the call from Chicago.

As CDC initiates its response protocols, the epidemic continues to progress, following a predictable amplification pattern of amplification. There is approximately a fourteen-day period from infection to full-blown disease, and one infected person will pass the disease to between 3 and 5 other people. In Little Rock, where the number of high-rise sealed buildings is less in comparison to the other affected cities the anticipated second wave of the epidemic there will comprise 45 infected people. The third wave will result in 135 infected individuals if no measures are taken.

In the Greater Cincinnati area, the second wave would produce 250 cases. The third wave would result in 1000 to 1250 cases and the fourth in 4000 to5000 cases if no steps are taken to control the disease. In fact, in natural epidemics, as awareness of the outbreak spreads, people naturally tend to isolate themselves so that by the fourth wave, a drop off might be expected.

In Chicago the small number of family members living with the flight crew members coupled with the airline company policy of removing them from flight status at the first signs of any disease produce a second wave of 12 infected people and a third wave of 45.

Historically the case fatality rate for classic smallpox varied between 20 and 60 percent. Morbidity was also substantial with many people scarred or blinded. The case fatality rate tends to be higher among children, particularly those under the age of five. The mortality rate for this scenario is 30% overall but 55% among small children.

SCENARIO ASSUMPTIONS

The scenario has been designed to provide a framework within which to examine possible national response to a smallpox outbreak. It is not designed to pick a "most probable scenario" or a best or worst case scenario but rather to provide an initial manageable situation in which to look at problems resulting from such an incident. For this reason, the most common historical transmission rates have been used.

It is very important to note how sensitive the estimates of infected persons are to the infectivity rate or assumption that the disease is passed on to between 3 to 5 and people per case.

A case can be made for a higher rate of infectibility. During the first wave of the 1972 Yugoslavian outbreak, Ljatif M infected 38 other people. It should be noted however that he had the hemorrhagic variety of smallpox in which more virus is shed than in classic smallpox. The same is true of the electrician returning from Karachi in 1970 who while hospitalized in Meschede Germany infected 19 persons, some of whom he had no direct contact with.

Classically smallpox was passed on to close family members because the preceding viremia often sent people to bed. In today's American workaholic culture, particularly in large cities, people may bring flu-like symptoms to work, particularly if the infected individual has mild symptoms. Additionally, apartment buildings, hospitals and offices are sealed and have closed ventilation systems. The experience at the Meschede hospital where the disease was obviously transmitted through the HVAC systems could be used to argue that a higher infectivity multiplier should be used in a susceptible population; and it can be argued that the US population today is more susceptible than either that of Germany or Yugoslavia in the outbreaks referred to. There are no clearly superior data from which to extrapolate. However, it is not the purpose of this scenario to arrive at a correct prediction of transmission rates.

APPENDIX E

BREAKOUT GROUP QUESTIONS

Questions for Breakout Groups in CDC/DOD Smallpox Workshop

Group 1 – Vaccination Strategies (contact vaccination)

1. What criteria would you use to initiate some form of vaccination?
2. What criteria would lead you to focus on contact vaccination?
3. How would you implement this strategy?
    a. Personnel requirements
    b. Training
    c. Contact tracing
    d. Place(s) of vaccination (centralized or in field)
    e. Follow-up for vaccine take/AEs
    f. Criteria for VIG use
    g. Screening for latent contraindications (HIV, pregnancy, etc.)?
    h. Alternatives for populations with contraindications
    i. Segments of Population that refuse vaccine
4. Identify other populations besides face-to-face contacts should be considered for vaccination in this strategy?
5. What percentage of the existing vaccine stores should not be exceeded for vaccinating non-contacts?
6. At what point does contact tracing become impractical/impossible?
    a. Specific case/contact tracing personnel ratio
    b. Specific case #
    c. Specific time period where there are no indications for a decline in cases or control of the outbreak

Group 2 - Vaccination Strategies (expanded vaccination)

1. What Criteria would lead you to focus on expanded vaccination?
2. How would you implement this strategy?
    a. Personnel requirements
    b. Training
    c. Place(s) of vaccination
    d. Follow-up of vaccinees for vaccine take/AEs
    d. Criteria for VIG use
    e. Screening for latent contraindications (HIV, pregnancy, etc.)?
    f. Alternatives for populations with contraindications
    g. Segments of Population that refuse vaccine
3. How would you prioritize populations for vaccination?
4. What control measures would you implement if vaccine stores were exhausted?
5. Under what circumstances would you chose this vaccination strategy over others?
    a. Specific case/contact tracing personnel ratio
    b. Specific case #

c. Specific time period where there are no indicators for a decline in cases or control of the outbreak
d. Ample stores of vaccine alone
e. Ample stores of vaccine and VIG

Group 3 – Local/State Surveillance

1. How will you initiate active surveillance for cases?
2. What are the parameters you will use to set up this system?
    a. Case definitions (confirmed, suspected, etc.)
    b. Frequency of reporting
    c. Type of data collected for reporting
    d. Source of data (collected by hospital personnel or health department personnel)
    e. Method(s) of reporting (fax, internet, telephone, etc.)
    f. Other parameters (size of outbreak)
3. What personnel resources would you anticipate would be needed for this surveillance system?
    a. Number of personnel
    b. Training of personnel
    c. Other requirements
4. Other issues
    a. Transportation nodes
    b. Communication with the Public

Group 4 – National Surveillance

1. How will you initiate national surveillance for cases?
2. What are the parameters you will use to set up this system?
    a. Case definitions (confirmed, suspected, etc.)
    b. Frequency of reporting from states
    c. Type of data reported from states
    d. Method(s) of reporting (fax, internet, telephone, etc.)
    e. Other parameters (size of outbreak)
3. What personnel resources would you anticipate are needed to coordinate national surveillance for this outbreak?
    a. Number of personnel
    b. Training of personnel
    c. Other requirements

4. Other issues
    a. Transportation nodes
    b. Communication with the Public
    c. Disease confirmation

Group 5 – Quarantine/Isolation Issues – Small number of initial cases

1. How will you isolate cases initially?
2. What guidance will be given to people that develop symptoms?
3. At what point would your strategy(s) for isolation of cases change?
   a. Number of cases?
   b. Specific time period where there are no indicators for a decline in cases or control of the outbreak?
   c. Amount of vaccine available?
4. What strategy(s) for quarantine/isolation of contacts will you employ?
5. At what point would your strategy(s) for quarantine/isolation of contacts change?
   a. Number of contacts or cases?
   b. Specific time period where there are no indicators for a decline in cases or control of the outbreak?
   c. Amount of vaccine available?
6. What legal authorities will you use to initiate your quarantine/isolation strategies for cases and contacts?
7. How will you enforce quarantine/isolation?
8. How would you communicate to the public?
9. How would fatalities by handled?
10. What actions would be taken at transportation nodes?

Group 6 – Quarantine/Isolation Issues – Large number of initial cases

1. How will you isolate cases initially?
2. What guidance will be given to people that develop symptoms?
3. At what point would your strategy(s) for isolation of cases change?
   a. Number of cases?
   b. Specific time period where there are no indicators for a decline in cases or control of the outbreak?
   c. Amount of vaccine available?
4. What strategy(s) for quarantine/isolation of contacts will you employ?
5. At what point would your strategy(s) for quarantine/isolation of contacts change?
   a. Number of contacts or cases?
   b. Specific time period where there are no indicators for a decline in cases or control of the outbreak?
   c. Amount of vaccine available?
6. What legal authorities will you use to initiate your quarantine/isolation strategies for cases and contacts?
7. How will you enforce quarantine/isolation?
8. How would you communicate to the public?
9. How would fatalities by handled?
10. What actions would be taken at transportation nodes?
11. Would public facilities remain open?

APPENDIX F

BREAKOUT GROUP OUTBRIEFS

Vaccination Strategies: Contact Vaccination

Overview

- **General rather than specific**
  - **Adapted and tailored by locals**
- **Ideas for products**
- **No need for indiscriminate vaccination**

1 - What criteria would you use to initiate vaccination?

- Unannounced - a "confirmed" case
  - Clinically compatible
  - Lab (CDC or RIID)
    - PCR, viral isolation, EM
- Announced
  - Best judgement - case by case
  - Risk assessment
    - Environmental vs clinical sample indicating potential for human exposure
- Consultation/early activities

2 - What criteria would lead you to focus on contact vaccination?

- ***Always*** **focus on contact vaccination, given confirmed diagnosis of smallpox**
- **Indiscriminate vaccination is not advised**
- **When risk-benefit analysis is abandoned in favor of indiscriminate vaccination, medical community loses control**
- **See also question 6**

3 - How would you implement a contact vaccination strategy?

3a - Personnel requirements

- **Medical training**
  - **Doctors, nurses, vets, military medical or public health officers**
- **Epidemiological training**
  - **Ideally, experience with STDs, measles, TB, or menigiococcal meningitis**
- **Social work skills**
  - **Ability to gain trust and obtain information from strangers**

3b- Training

- **Vaccination training is relatively simple (personnel can be trained in a few hours)**
- **Need a pre-written memo on who can (legally) administer vaccine**
- **Need a pre-established roster of qualified vaccinators**

3c - Contact tracing

- **Must maintain critical medical infrastructure; cannot pull contact tracers only from medical community**
- **Use media as an adjunct to disseminate information**
    - **Communicate that there is no specific medical treatment**
- **More difficult to teach contact tracing**
- **Law enforcement skills**
    - **Proficiency in obtaining information Law enforcement can help obtain information that is legally or otherwise restricted, e.g., flight roster**

3d - Place(s) of vaccination

- **Large event - (pre?)designate a central facility for vaccination, e.g., mall, school**
- **Smaller event**
  - **Vaccinate at interview site to save time and ensure compliance**
  - **Need to address requirements for consent, dissemination of information, and whether it is compulsory**
  - **Don't have missed opportunities**
    - **Contact tracers must be vaccination qualified**

3e - Follow-up for vaccine take

- **Need to document vaccination and take**
  - **Follow up in 6-7 days**
    - **Phone call**
    - **Place for referral**
    - **Info on imminent symptoms/ what to expect**
  - **Need international agreement on what constitutes documentation**
- **Follow-up for fever by phone**
    - **Pts with thermometers, are skilled at reading them, and are compliant with taking temperature readings**

3f - Criteria for VIG use

- **Contraindications/indications should be standardized**
  - **Given only to recipients designated by the state health director**
- **Lower rates of complications in patients with risk factors who were given VIG**
  - **However; reserve VIG for patients who have complications from vaccine, e.g. vaccinia necrosum, eczema vaccinatum**

3g - Screening for latent contraindications

- **There are *no* contraindications for direct face-to-face contacts**
- **Vaccine may be contraindicated for some individuals**
  - **patients with eczema, immunosuppression, or pregnancy who are contacts of contacts**
- **Information on contraindications and special precautions should be provided regularly and consistently**

3h - Alternatives for populations with contraindications

- Patients with contraindications have no recourse other than removal from environment and fever watch
- CDC should produce information on vaccine contraindications
  - Pamplet
  - Press release
  - Web site
  - Hot line
- Publications should be in agreement

3i - Segments of population that refuse vaccine

- **Cannot force someone to accept vaccination**
- **However, a person can be put into forced isolation (quarantine) to prevent further spread of disease**
- **VIG or antivirals should *not* be given to those who refuse vaccination**

4 - Other populations who should be vaccinated

- **Target those at risk for contact**
  - **Medical or other care-giving personnel**
  - **First responders and other response teams**
  - **Laundry and mortuary personnel**
  - **Clergy or elected officials who may desire contact with infected patients**
  - **Lab technicians performing diagnostic tests**
- **See guidelines for pandemic influenza**
- **Decisions are case-by-case and dependent on situation**

4 - Other populations (cont.)

- **Need to prioritize who in the occupational risk group**
  - **Reasonable assessment**
  - **Those with prior vaccination**
  - **Establish/discuss policies now**

6 - When does contact tracing become impractical?

- **Never - As number of cases increases**
  - **Tracing becomes sloppier**
  - **Definition of "contact" becomes looser and less discriminating**
- **Indiscriminate vaccination is *never* advised (although political, social, and media pressure may influence otherwise)**
- **Giving up risk-benefit decisions means surrendering medical control: *Primum non nocere***

Issues Related to Mass Vaccination

Residual issues

- **Increased rate of post-vaccinal encephalitis if <1 y/o**
  - A relative contraindication
- **Advertise in media routine after-care**
  - No abx, what to expect-appearance, dressing
- **Educate HCP's on expectation after vaccination**
  - Generalized rash, low-grade temp
  - Modest home isolation and watch for evolution of rash

No indication for mass vaccination Recognize: Hands may be forced

- **Educate politicians in advance**
  - Not to “jump the gun” with the public
  - Problems with risk/benefit of vaccination
  - Can do more harm with potentially delaying vaccination of contacts
  - More immunocompromised than HIV
    - Transplant, steroids, ESRD
  - Risk of spread by bringing ill personnel into large crowds
  - Pulling limited contact tracers into a mass vaccination effort
- **Media critical**
  - To prevent inappropriate demand
  - If has to be done, ensures mass vaccination done right

How to protect individuals with contraindications against vaccinia

- Public announcements
- Placard at vaccination site
- Screening form - Best, allows for documentation

Limitations

- **Vaccination can be done very quickly**
- **Documentation is the rate-limiting factor**
  - Need 5-6 clerks per vaccinator
  - People fill out info. in line
    - Standardized form
    - Multiple languages
    - Basic info. to minimize error rates
- **Needle sterilization issues**

Limitations (Cont.)

- **While in line - use as educational opportunity**
  - Photos of smallpox
  - Signs and symptoms
  - Info. on contraindications

How to document vaccine for those departing the area

- **In the best mass effort, lucky to get 80%**
- **Some fleeing the area**
  - Contraindicated
  - Some anti-vaccines
  - Some “undocumented”

Indemnification

- How to cover the vaccinators/manufacturers against liability
- What about others who loan their facilities or time
  - The motel owner

LOCAL/STATE SURVEILLANCE

Local/State Surveillance

- 1. How will you initiate active surveillance for cases?
- 2. What are the parameters you will use to set up this system?
  - **a. Case definitions (Agent Specific)**
    - **>100 F Fever with Rash at present or within last 2 weeks**
    - **Pharmaceuticals Prescribed/Issued for Chicken Pox**
    - **Number of Suspected Cases of Chicken Pox**
    - **Reports of Rashes**
    - **Peripheral Rash Spreading to Core**

Local/State Surveillance (cont.)

- 2. What are the parameters you will use to set up this system? (continued)
  - **b. Frequency of reporting**
    - **Immediate Report of Suspected Cases**
    - **Daily Update - Areas not immediately affected**
    - **Active Regional Surveillance**
      - *** Hospitals**
        - **- ER's**
        - **- Infectious Control Personnel**
      - *** Clinics**
      - *** Private Practitioners**

Local/State Surveillance (cont.)

- 2. What are the parameters you will use to set up this system? (continued)
  - **c. Type of data collected for reporting (Shared with other Agencies)**
    - **Admission Sheet Data - Personal Information**
    - **Travel History**
    - **Description of Symptoms**
    - **Identify those Cases being treated by Dermatologist**
    - **EMS Runs & Transportation Refusals**
    - **Identify Contacts / Family Members**
    - **Reports (Anonymous or based on Suspicion)**

Local/State Surveillance (cont.)

- 2. What are the parameters you will use to set up this system? (continued)
  - **d. Source of data (collected by hospital personnel or health department personnel)**
    - **EMS**
    - **Health Department**
    - **UHF/VHF EMS Broadcasts**
    - **Health Care Workers**
    - **Medical Examiners (Unexplained Deaths)**
    - **Dermatologists**
    - **Laboratories**
    - **Pharmacies**
    - **Morticians**
    - **Transportation (Air / Land / Sea)**

Local/State Surveillance (cont.)

- 2. What are the parameters you will use to set up this system? (continued)
  - **e. Method(s) of reporting (fax, internet, telephone, etc.)**
    - **Fast and Accurate**
      - *** Fax**
      - *** Phone**
      - *** Electronic Mail**
      - *** Internet (Website)**

Local/State Surveillance (cont.)

- 3. What personnel resources would you anticipate would be needed for this surveillance system?
  - **a. Type of personnel**
    - **Epidemiologists**
    - **Epidemiology Trained Personnel**
    - **Medical Clerks**
    - **Emergency Management Team**
      - *** Legal**
      - *** Communication / PIO's**
      - *** Social Workers**
    - **Medical Students**
    - **Public Health Investigators**
    - **Volunteers Organizations (e. g. - Red Cross, Salv. Army)**

Local/State Surveillance (cont.)

- 3. What personnel resources would you anticipate would be needed for this surveillance system? (continued)
  - **b. Training of personnel**
    - **Awareness of Bio Terrorism**
    - **Communications**
      - *** Public Health Officers & Hospitals**
      - *** Health Community & Other Agencies**
    - **Agent Characteristics**
      - *** Chicken Pox v. Smallpox**
    - **Data Collection (Questionnaire)**
    - **Media Issues**

Local/State Surveillance (cont.)

- 3. What personnel resources would you anticipate would be needed for this surveillance system? (continued)
  - **b. Training of personnel (continued)**
    - **Confidentiality**
    - **Personnel Protection**
    - **Lessons Learned**
    - **Roles & Responsibilities**
    - **Table Top Exercises**
    - **Tracking Tools (Software)**
    - **Competence**

Local/State Surveillance (cont.)

- 4. Other issues
  - **a. Transportation nodes**
    - **More relevant at the National / International Level**
  - **b. Communication with the Public**
    - **Frequent Reporting**
      - *** Facts**
      - *** Precautions**
      - *** Instructions / Recommendations**

NATIONAL SURVEILLANCE

National Surveillance

- 1. How will you initiate national surveillance for cases?
- 2. What are the parameters you will use to set up this system?
  - **a. Case definitions (confirmed, suspected, etc.)**
    - **Laboratory Confirmed Cases – CDC / USAMRIID**
    - **Fever with Pustular Rashes**
  - **b. Frequency of reporting from states**
    - **Frequent, Situation Specific**
  - **c. Type of data reported from states**
    - **Number of Cases**
    - **Basic Demographic Data**

National Surveillance (cont.)

- 2. What are the parameters you will use to set up this system? (continued)
  - **d. Source of data (collected by hospital personnel or health department personnel)**
    - **State Public Health**
  - **e. Method(s) of reporting (fax, internet, telephone, etc.)**
    - **Multiple Methods**
      - *** Fax**
      - *** Phone**
      - *** Electronic Mail**
  - **f. Other parameters**
    - **No. of Case Related Deaths**
    - **Sequelae Long-Term Surveillance**

National Surveillance (cont.)

- 3. What personnel resources would you anticipate would be needed for this surveillance system?
  - **a. Type of personnel**
    - **Surveillance Trained Personnel**
    - **Analysts**
  - **b. Training of personnel**
    - **Tracking Tools (Software)**
    - **Competence**
  - **c. Other requirements**
    - **Increased Electronic Data Transit**
    - **System Setup & Maintenance**

National Surveillance (cont.)

- 4. Other issues
  - **a. Transportation nodes**
    - **Activate Emergency Screening Procedure**
    - **Enhanced Surveillance**
  - **b. Communication with the Public**
    - **Frequent Reporting**
      - *** No of Cases**
      - *** Outbreak Data**
        - **- Size**
        - **- Location**
      - *** Travel Bulletins**

Quarantine & Isolation

Small Number of Cases

Areas of Focus

- Isolation Groups and Options
- Guidance for Those with Symptoms
- Isolation Strategy Change
- Legal Authority for Isolation
- Enforcement of Isolation
- Action at Transportation Nodes
- Fatality Management
- Public Communication

Isolation Groups

- Suspected Initial Case(s)
- Possible Cases Due to Heightened Awareness
- Close Contacts
- Questionable Contacts
- Unexpected Cases

Isolation Options

- Suspected Initial Cases
  - Have rash/high fever/lesions
  - Hospital with negative pressure room
  - Room should meet OSHA/JCAHO/TB standards
  - Use standard precautions

Isolation Options (cont.)

- Possible Cases Due to Heightened Awareness
  - Walk-in patients with similar symptoms; identified due to suspected cases
  - Treat the same as Suspected Initial Case(s)
  - Place in separate room(s) from Suspected Initial Case
  - May want to cohort if lack sufficient space/facilities

Isolation Options (cont.)

- Close Contacts (face-to-face)
  - Isolate at home
  - Send public health personnel to conduct investigation
- Questionable Contact (casual)
  - No action
- Unexpected Cases
  - Re-evaluation of previous walk-ins; may have been sent home or currently in hospital
  - Treat like close contacts

Isolation Options-Special Situations

- Too many people without support structures
- Too dense an environment for "home" care

Guidance for Those with Symptoms

- Call Your Doctor First for Examination
- Contact the Public Health Department
- Stay at Home
  - No contact with anyone
  - Family should stay at home with you
- On-Site Contact Management

Isolation Strategy Change

- Small Number of Cases Defined - Hospitals can cope with the number of cases & contacts without activating their emergency plan
- Factors that Change Strategy
  - Limited vaccine
  - Control measures are not working
  - No decline in new cases
  - Unexpected signs of transmission (new locations)
  - Failure of vaccine
  - Inability to enact control measures/public rejection

Legal Authority for Isolation

- Authority Should Allow for Due Process without Encumbering the Control Strategy or Increasing the Risk to Public Safety
- Elements of Authority
  - Should limit individual(s) ability to move/infect others
  - Should empower public health to require treatment/vaccination
  - Should limit individual's ability to expose themselves
  - Should enact the power to enforce the isolation
  - Should make provisions to meet the needs of those in isolation - i.e., food, water, medical, etc.

Enforcement of Isolation

- Individual Intervention - No Large-Scale Need for Enforcement Seen
- State/Local & Federal Work Together to Enforce
- Primary Law Enforcement Roles
  - Security for public health personnel
  - Security for supplies
  - Crowd control at transportation nodes

Action at Transportation Nodes

- Initiate Surveillance at All Major Nodes
  - Airports
  - Bus & Train Stations
  - Harbors
- No One Is Allowed to Leave Until They Are Screened

Fatality Management

- Medical Examiner Cases
- Controlled handling of remains
  - Handle with BSL-3 (4?) precautions
  - Package as infectious waste
  - Special collection teams-vaccinated
- Incineration preferred (good crematoria)
- Sealed casket interment (discouraged)
- Review legal authority to control remains

Public Communication

- What
  - Basic information on outbreak
  - Basic information on disease
    - Describe nature of disease
    - Tell how spread
    - Tell how to limit spread
    - Some general information on case
  - Information to build credibility
    - Know some more cases
    - On top of it

Public Communication

- What (continued)
  - Basic information on isolation
    - Protect you
    - Protect ones close to you
    - Protect community
  - Actions in progress
    - Contact management

Public Communication

- Work (continued)
  - What to expect
    - How we do outbreaks
    - How do we intervene with people
    - Who will be treated
  - When & what you will hear again
    - Back in 24 hours

Public Communication

- How
  - Use 3rd party to establish credibility
  - Broadcast media for immediate/most critical information
  - Print media/internet
  - Health Alert Network for medical community assistance
  - HOTLINES
  - Community networks
  - Internet

Public Communication

- Who
  - Single credible spokesman
    - Chief health official
  - Use 3rd party to establish credibility (if needed)
  - Coordinate responses with health care facilities and other sources of information

Public Communication

- When
  - Per Unified Command System PIO
  - Respond to inquiry
  - When there is need for control

APPENDIX G

TEMPLATE VALIDATION WORKSHEETS

Continuous Surveillance Activities

Communicable Diseases	Sample Activities
Added key indicators -School absences -Increase in reportable diseases	Monitor key Indicators - Hospital admissions - Unexplained deaths - 911 call volume - Flu medication sales - Unusual animal diseases and deaths - EMS activities - Employment absentee above baseline

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

Expanded Surveillance Activities

Communicable Diseases	Sample Activities
Added Active Data Collection Polls -Poll pharmaceutical distribution points	Active Data Collection - Poll hospital departments and ER's - Poll EMS activities - Poll pediatricians, infectious disease practitioners, family practice physicians and community clinics - Poll medical examiners - Poll veterinary clinics and zoos - Poll poison control centers - Poll employment absentee levels - Poll USDA on herd-flock health information

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

Medical Diagnosis Activities

Communicable Disease	Sample Activities
No recommended changes	1. Undertake clinical lab tests
	2. Obtain presumptive diagnosis and preliminary laboratory identification of illness
	3. Ship samples to CDC/USAMRIID and to USDA/FADDL if animal, plant or food associated illness
	4. Confirm diagnosis and agent ID at CDC/USAMRIID/USDA
	5. Obtain veterinary diagnosis (as applicable)

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

Epidemiological Investigation Activities

Communicable Diseases	Sample Activities
After “gathering”, add /contact tracing	1. Conduct standard information gathering efforts (standard questionnaire)
	2. Establish case definition and continuously update with new information
	3. Analyze the distribution of cases, places, and time (humans, animals, plants, insects) - Chart spatial/temporal course of the outbreak - Define and map the population at risk and map initial victim locations - Trace movements of humans, animals, plants, insects, foods and medical personnel - Identify the source, mode of transmission, and cause
	4. Analyze the risk factors (commonality)

	5. Collect clinical/environmental information - Collect and analyze clinical specimens from humans, animal, plant, insects (as applicable) - Collect and analyze samples of food, water and air (as applicable) - Conduct interviews
	6. Analyze clinical and environmental information, diagnosis and prognosis
Added recommendations -Evaluate control measures -Recommend protective measures for key personnel and response personnel -Develop immunization strategies, as required	7. Recommend measures for containment, prevention, and treatment (human, animal, plant, insect, food, water and air) - Develop hypothesis - Recommend control measures - Communicate results
	8. Conduct threat assessment and share information with other communities/agencies

	9. Interface with criminal investigation and exchange epidemiological information continuously through out the incident

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

Criminal Investigation Activities

Communicable Disease	Sample Activities
Add major activity. Implement protective measures for investigators.	1. Activate investigation task force
	2. Conduct interviews - Hospital staff and patients - Airport/bus/train station employees - Sick officers and security personnel - Marine workers
	3. Establish tip-line
	4. Collect Evidence - Unexplained powder/liquid residue, dissemination devices, etc. - Air filters
	5. Interface with epidemiological investigation and exchange information throughout the investigation
	6. Identify, locate, and apprehend suspects

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

Local Command and Control Activities

Communicable Disease	Sample Activities
Add major activity 6. Request state disaster declaration.	1. Activate local EOC
	2. Activate unified medical command
	3. Request local, state, and federal agency representatives (liaisons) for EOC
	4. Implement local emergency ops plan
	5. Declare a local State of Emergency

Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
L = Current local capability	

State Command and Control Activities

Communicable Disease	Sample Activities
Delete “companies”	1. Provide representatives to local EOC & FBI JOC (as requested)
	2. Activate state EOC
	3. Implement the state emergency ops plan
	4. Activate National Guard companies
	5. Declare state Disaster Declaration
	6. Request Presidential Disaster Declaration
Indicate response capability or shortfall next to each activity:	
F = Current federal capability	LC = Limited capability (needs enhancement)
S = Current state capability	N = No adequate capability (any level)
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Federal Command and Control Activities

Communicable Disease	Sample Activities
Add major activity 15. Deploy Federal medical assets.	1. Provide representatives to local and state EOC (as requested)
	2. Activate FEMA Regional Ops Center
	3. Activate FEMA Emergency Support Team
	4. Activate FEMA Disaster Field Office
	5. Activate and deploy Emergency Response Team - advance ERT-A
	6. Convene Catastrophic Disaster Response Group (CDRG)
	7. President declares disaster under the Stafford Act
	8. Appoint state, federal, and defense coordinating officers
	9. Activate FBI command post
	10. Activate FBI Joint Terrorism Task Force
	11. Activate JOC and SIOC
	12. Appoint FBI On-scene Commander

	13. Deploy critical incident response group
	14. Deploy C/B tailored DEST

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Residual Hazard Mitigation & Control Activities

Communicable Disease	Sample Activities
	1. Conduct environmental sampling (air, water, soil, surface swipes, animals, insects, plants as applicable).
Add major activity between 2 and 3 Conduct control measures and decontamination at facilities and sites, as appropriate.	2. Conduct local area control and decontamination. (as applicable)
	3. Perform vector, animal, plant, water and air control measures as applicable.
	4. Control food sources and processed foods as applicable.
	5. Dispose of contaminated animals, plants and food as applicable.
Add “law enforcement”	6. Provide personnel and equipment support to sampling and decontamination teams.

Indicate response capability or shortfall next to each activity:	
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Mass Prophylaxis Activities

Communicable Disease	Sample Activities
Change title of template to **"Immunization and Prophylaxis Activities"**	1. Activate medical prophylaxis plan.
	2. Distribute prepackaged medication via: - Mass distribution sites (e.g., NEHC) - Door-to-door Canvas (e.g., Community Outreach) - Other means (e.g., mail)
Add major activity. 3. Immunization at community centers, homes, and other places (as determined).	
Add major activity. 4. Arrange for security, as required.	
Add major activity. 5. Control critical pharmaceuticals.	

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Care of Casualties Activities

Communicable Disease	Sample Activities
Delete first sub activity. Replace with: Admit patients until best treatment facilities are determined.	1. Provide care to initial patients: - Admit casualties until hospitals are full - Activate hospital internal disaster plans
Change “Emergency Medical System” to “Modular Emergency Medical System”	2. Activate Emergency Medical System - Notify affected personnel and facilities - Request State and NDMS support
Add “subordinate” prior to “medical command”	3. Establish medical command centers in community hospitals (e.g., MCC)
	4. Provide medical regulation - Provide medical traffic management - Allocate vehicles and staff - Coordinate and direct movement - Determine “level of treatment”

Add "…,as required" following "(e.g., NEHC)" Add at end of first sub activity, "or infectious patient." Add "hotels" to possible sites.	5. Establish casualties collection sites to assess and triage casualties (e.g., NEHC) - Provide triage to separate worried well from acutely ill - Register all incoming patients - Send acutely ill to a definitive care facility (e.g., hospital or ACC) - Send walking ill and worried well home with medication and self-help instructions - Provide emergency treatment to stabilize for transport to definitive care Possible sites: clinics, fire houses, halls, churches, malls
	6. Establish ancillary acute care facilities to expand definitive care capability (e.g. ACC) - Provide care to acutely ill - Provide treatment - Provide hospice care to terminally ill - Possible sites: nursing homes, hotels, shelters, office buildings - Provide childcare for staff

Add "(Particularly important for communicable diseases)" after "outreach" Add sub-activities to 7. -Initial contact tracing Change 3rd sub-activity to: Distribute medication/administer vaccine and self help instructions. Add major activities. 9. Implement protective measures for health care personnel.	7. Establish community outreach: - Initial surveys to assess the situation - Full neighborhood canvas to provide home bound assistance -Distribute medication and self-help instructions 8. Establish a medical transportation control Center and staging sites (e.g., CRU) - Dispatch - Staffing - Maintenance/Fueling - Ambulance/Bus, Air, Rail - Transport severely ill BW patients to care facilities - Home bound casualties to medical care - Acutely ill casualties from collection sites to definitive care facilities - Transport non BW infected area hospital patients to other facilities - Identify destinations for patient relocations

New activity. 10. Established and initiate infection control measures, as needed. -Education and infection control -Minimize public gatherings -immunize, prophylaxis, limit contact to control spread -Closing schools—immunize face-to-face contacts -isolation, quarantine, etc. to minimize spread of infection -Use of personal protective apparel -Minimize exposure (by use of above) and disinfection, disposal and hand washing techniques	

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Control of Affected Area & Affected Population Activities

Communicable Disease	Sample Activities
	1. Implement physical control plan
Add: Limit public gatherings, e.g., close schools, sporting events, etc.	2. Conduct crowd control - Provide security at hospitals - Provide security at casualty collection sites and at ancillary care sites - Provide security at central morgue facilities and temporary fatality sites - Provide security at quarantined premises (animal, plant, food)
Add: Limit mass transportation (for communicable diseases) e.g. air terminals, railheads, bus terminals, etc. Do not prohibit individual travel, but obtain tracking information.	3. Conduct traffic control - Provide control of critical ingress/egress routes and post to public information - Provide escorts for emergency medical equipment, supplies, and personnel

	- Provide emergency lanes for essential workers - Establish checkpoints and enforce quarantine of animals, plants and foods.
	4. Patrol affected area
Add sub activities -Health care facilities -Pharmaceutical storage sites	5. Provide security at vital installations - Airports - Bridges - Communications/utility sites
	6. Implement public information/rumor control plan.
	7. Review existing public information materials; revise and reproduce
	8. Establish and operate a locate incident help-line (1-800)
	9. Post official incident media release - Television - Radio - Newspaper - Internet
	10. Distribute incident self-help fact sheets on human care and preventive measures.

Replace “Emergency Broadcast System” with “Emergency Alert System”	11. Place Emergency Broadcast System on standby
Change “Joint Information Center (JIC)” with “Central Information Center”	12. Conduct senior officials press conference
	13. Establish the Joint Information Center (JIC)
	14. Identify a single spokesperson
	15. Establish PAO information network
	16. Gather incident information
	17. Monitor news coverage
	18. Conduct scheduled PAO staff briefings
	19. Provide joint press releases (2 per day)
	20. Respond to media requests

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Resource & Logistic Support Activities

Communicable Disease	Sample Activities
	1. Establish mobilization centers and distribution points (PODs) - Air - Ground - Sea - Rail
	2. Activate FRP ESF #7 - Resource Support
	3. Activate FRP ESF #1 - Transportation
	4. Establish transportation coordination center
	5. Develop statements of needs and prioritize equipment, personnel, and services
	6. Provide local delivery to users from POD
	7. Establish centralized reception center for support personnel - Instruct - Accredit - Assign

Add “and to home isolated victims.”	8. Provide housing, feeding, sanitation to emergency responders

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Fatality Management Activities

Communicable Disease	Sample Activities
	1. Make decision not to release remains
	2. Maintain mortuary registry of like deaths
	3. Admit remains until local morgues reach capacity
	4. Communicate and respond to requests of families seeking remains
	5. Convert regional morgues to provide high volume central processing of fatalities
	6. Establish long-term high capacity storage facilities for incident related remains
Change 2nd sub activity to: "Conduct burial (Sealed container mandatory for communicable disease)" Change 3rd sub activity to: "Conduct cremation (Preferred for communicable disease)"	7. Determine final disposition of remains - Conduct release to families - Conduct mass burial - Conduct mass cremation

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Continuity of Infrastructure Activities

Communicable Disease	Sample Activities
Delete “command” Add “…including protective measures.”	1. Activate continuity of operations plan when absenteeism exceeds critical threshold
	2. Close business offices to minimize contact with public
	3. Activate alternate operating facilities
	4. Maintain essential operations
	5. Activate employee information network
	6. Identify critical personnel and issue them personal protection
	7. Identify essential command personnel and request priority treatment
	8. Activate mutual aid among industry
	9. Sustain high tempo emergency services
	10. Implement emergency staffing plan
	11. Use non-conventional resources to transport response personnel
	12. Prepare situation briefing, updates, reports

	13. Provide critical incident stress mgmt to responders and their families -Telecommunications -Water -Sanitation

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Family Support Services Activities

Communicable Disease	Sample Activities
No recommended changes.	1. Implement public information system - Hotlines - Medical information fact sheets
	2. Implement centralized volunteer service coordination center
	3. Provide non-medical victim assistance
	4. Conduct notification of NOK
	5. Provide crisis counseling
	6. Provide logistic support to families
	7. Provide legal services to victims
	8. Provide insurance information assistance
	9. Provide translator services
	10. Provide State Dept. liaisons to foreign victims

	11. Implement state and federal assistance programs
	12. Activate disaster assistance center
	13. Provide temporary housing assistance
	14. Provide victim financial assistance
	15. Conduct a community memorial service

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APPENDIX H

ABBREVIATIONS

ABBREVIATIONS

AARP	American Association of Retired People
APIC	Association for Professionals in Infection Control and Epidemiology
BSL	Biological Safety Level
BW	Biological Warfare
CDC	Centers for Disease Control and Surveillance
CST	Civil Support Team
DHHS	Department of Health and Human Services
DMORT	Disaster Mortuary Operational Response Team
DOJ	Department of Justice
EMS	Emergency Medical Service
ER	Emergency Room
FBI	Federal Bureau of Investigation
FEMA	Federal Emergency Management Agency
HIV	Human Immunodeficiency Virus
HVAC	Heating, Ventilation and Air Conditioning
ICP	Infection Control Professional
IRP	Improved Response Program
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JIC	Joint Information Center
MMRS	Metropolitan Medical Response System
NDMS	National Disaster Medical System
NEHC	Neighborhood Emergency Help Center
OSHA	Occupational Safety and Health Administration
OTC	Over the Counter
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
SBCCOM	U.S. Army Soldier and Biological Chemical Command
STD	Sexually Transmitted Disease
TB	Tuberculosis
UHF/VHF	Ultra High Frequency/Very High Frequency
USAMRIID	U.S. Army Medical Research Institute for Infectious Diseases
VIG	Vaccine Immune Globulin
WHO	World Health Organization
WMD	Weapon of Mass Destruction